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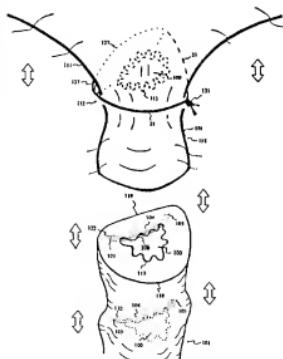
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(54) Title: NON-INVASIVE AND MINIMALLY INVASIVE METHODS AND DEVICES FOR TREATING URINARY INCONTINENCE OR OBSTRUCTION



(57) Abstract: For treating urinary incontinence, an internal urethral support is inserted non-invasively through the opening of a urethra and anchored in the resilient mucosa to improve sphincteric closure during stress, by supporting and strengthening the urethra particularly its posterior wall. For open sphincters even at rest, the internal urethral support is also used as an internal urethral anchor, mounting a shape memory element, magnet or extensor, to close the urethral sphincter. In a minimally invasive surgery, the bladder neck and/or urethra are partially ligated to restrict the lumen opening and to improve closure capability. The restricted lumen is reproducibly sized and limited by a spacer inserted through the urethra. For urethral obstruction, similar urethral insertion devices can also be used to stretch and stiffen the urethral wall against an obstruction to widen the lumen opening from within and to promote urine flow.

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NON-INVASIVE AND MINIMALLY INVASIVE
METHODS AND DEVICES FOR TREATING
URINARY INCONTINENCE OR OBSTRUCTION

5

FIELD OF THE INVENTION

This invention relates to methods and devices to treat urinary incontinence and obstruction in both men and women by non-invasive and/or minimally invasive methods and devices. In the
10 non-invasive treatment, a device is inserted through the opening of the urethra and anchored in the mucosa to improve closure by supporting and strengthening the posterior wall of the urethra. In the minimally invasive treatment, the bladder neck and/or urethra are partially ligated to decrease the lumen opening and improve closure capability.

A similar urethral insertion device can also stretch and stiffen the urethral wall against an
15 obstruction to widen the lumen opening from within to promote urine flow.

BACKGROUND, TRADITIONAL TREATMENTS
AND PRIOR INVENTIONS

Prevalence and Cost of Urinary Incontinence

20 Urinary incontinence is one of the most common urinary dysfunctions. The number of people living with urinary incontinence is far higher than estimated, even by most primary care physicians. A report published by the Agency for Health Care Policy and Research of the U.S. Public Health Service estimates that at least 10 million, more likely 20 million, adult Americans are affected by urinary incontinence. Many patients, especially women, do not mention their
25 incontinence problems to their physicians. One of the reasons is that women are accustomed to using feminine hygiene products, some of which are designed for urine absorption. Among the elderly population, a 1975 report from the U.S. Department of Health showed that 55% of the surveyed patients living in long-term facilities had problems with urinary control. In Europe during 1980, a large postal survey of 22,430 people from ages 5 to over 85 showed that up to
30 8.5% of surveyed individuals had two or more episodes of urinary incontinent occurrences in a month. The percentage of women within the age groups who suffer from occasional incontinence is much higher (Raz S., *Female Urology*, 2nd Ed., W.B. Saunders Co., 1996, pp.73-74).

Although urinary incontinence is not a life threatening disease, many incontinent patients suffer intense embarrassment, loss of self-esteem, feelings of helplessness, limited travel, depression, anxiety, avoidance of sexual relationships and withdrawal from social contacts (Urology Times, February 1996; Hu T-W., J. Am. Geriatr. Soc., 38:292, 1990).

5 Urinary incontinence is costly to patients and the health care systems. Annual sales of adult disposable diapers reach half of a billion dollars. The cost of medication and medical intervention for infections initiated and/or promoted by urinary incontinence is significant with no accurate estimates. In nursing homes alone, services incurred by incontinence are estimated to be \$3 billion per year. The careers of the sufferers are often prematurely terminated or adversely affected by

10 the offensive odor. The financial and social impact from urinary incontinence are very real, significant and rapidly growing with our aging population.

Mechanism of Urethral Sphincter

The two major urinary closures in our bodies are the urethral sphincter and the bladder neck. The term "urethral sphincter," or "sphincter urethrae," is often referred to as some sort of valve to stop the flow of urine. However, unlike the valves of a heart, the urethral sphincter cannot be identified with the naked eye, even under a microscope. The interior layer of urethra is an integrated interaction between smooth and striated muscle with collagen and elastin forming spongy and supple mucosal folds, which drive the closure of the urethral lumen. The exterior or outer layer of the urethra provides structural and ligament support. A section of the urethral sphincter is depicted in Figure 1, with a longitudinal view shown in Figure 6. The external striated layer of the urethral sphincter consists of bundles of circularly arranged fibers with maximal density at the mid-urethral level anteriorly, thinning laterally and becoming almost totally deficient posteriorly (Gosling J. A., et al., J. Anat. 129:216, 1979; Stanton S. L., et al., Surgery of Female Incontinence, 2nd Ed., Springer-Verlag, NY., 1986, pp. 4-5). The slow-twitch muscle fibers primarily provide an involuntary urinary control; fast-twitch fibers are responsible for relaxation and voluntary sphincteric activity. Therefore, the sphincter is under partial voluntary control. (Raz S., Female Urology, 2nd Ed., W.B. Saunders Co., 1996, pp. 58-59).

The female urethra is between 30 and 50 mm in total length, including the sphincteric length of about 28 mm, with the lumen diameter about 5.3 mm. The sponge-like folding and suppleness of the resilient mucosa are promoted by sex hormone. With age and the decline of sex hormone, the mucosa at the middle and proximal portions of the urethra thins out (Stanton S. L., et al., Surgery of Female Incontinence, 2nd Ed., Springer-Verlag, NY., 1986, p. 5).

During stress from coughing, sneezing or suddenly increasing abdominal pressure, the tensile forces of the urethropelvic ligaments pull on the urethra laterally to collapse the opening of the lumen, as indicated in Figure 2. The spongy mucosa in the lumen forms a coaptive seal to prevent urine leakage (Raz S., Female Urology, 2nd Ed., W.B. Saunders Co., 1996, p. 66).

5 On the other hand, voiding is accomplished by the relaxation of pelvic floor muscles, contraction of detrusor muscles from the abdomen and increased tension of urethral muscles to shorten and widen the urethra (Lapides J., J. Urol. 80:341-353, 1958; Bradley W. E., et al., Urol. Clin. North. Am., 1: 3-27, 1974; Stanton S. L., et al., Surgery of Female Incontinence, 2nd Ed., Springer-Verlag, NY., 1986, p. 11).

10 Bladder outlet resistance is a complex mechanism that involves the bladder neck, proximal urethral smooth muscle, anatomic support of the bladder base and urethra. Circular fibers of smooth muscle are found at the bladder neck. It seems that passive elastic tension is the most important factor leading to closure of the bladder neck and proximal urethra.

15 The bladder neck and the proximal urethra retain sphincteric function unless they are damaged by disease, surgery, pregnancy or by the slow pull of gravity on the muscular and ligamentous supports (Campbell's Urology, Ed. P. Walsh et al., 7th Ed., Vol. 1, 1998, p.1007).

Factors Leading to Urinary Incontinence

20 The following elements are essential for apposition and coaptation of the mucosa: urethral wall tension, external compression, urethral support, adjustment during increased abdominal pressure and softness of mucosa (Zinner N. R., et al., Urology, 1980, 16:115; Campbell's Urology, Ed. P. Walsh et al., 7th Ed., Vol. 1, 1998, p.1017).

25 One of the most common beliefs of a leading cause of urinary incontinence is the loss of structural support for the urethra, especially behind the posterior urethral wall, which is indicated by hypermobility of the urethra. Gravity and/or pregnancy may have adversely affected the structural support. As a result, varying degrees of descent of the bladder neck and urethra lead to varying types of stress incontinence (Campbell's Urology, Ed. P. Walsh et al., 7th Ed., Vol. 1, 1998, p.1018; Walters M. D., J. Repro. Med. 1990, 35(8): 777-784).

30 The structural (anatomic) support of the muscle-poor posterior urethral wall serves as a backboard against which the urethra is compressed during increased abdominal pressure. Research studies using magnetic resonance imaging substantiate the importance of posterior support of the urethra. During stress in the incontinent patient, there is an unequal movement of the anterior and posterior walls of the vesical neck and urethra proximal to the bladder. The urethral lumen is

actually pulled open as the posterior wall moves away from the anterior wall; then leakage occurs (Mostwin J. L. et al., *Urol. Clin. North. Am.* 1995, 22(3): 539-549; Campbell's Urology, Ed. P. Walsh et al., 7th Ed., Vol. 1, 1998, p. 1018).

In men, sphincter abnormalities are most commonly caused by anatomic disruption after 5 prostate surgery, trauma or neurologic abnormalities. After radical prostatectomy, five to ten percent of the patients suffer from permanent urinary incontinence. In women, sphincter abnormalities may be classified in two ways: (1) urethral hypermobility, and (2) intrinsic sphincter deficiency. Urethral hypermobility is often caused by a weakness of pelvic floor support. During an increase in abdominal pressure, vesical (bladder) neck and proximal urethra rotationally descend 10 and slip away from the supporting tissue behind. (Campbell's Urology, Ed. P. Walsh et al., 7th Ed., Vol. 1, 1998, pp.1011-1012).

Incontinence that occurs during stress is not always caused by the lack of anatomic support or sphincter abnormalities. In some patients, the stress initiates an abdominal detrusor contraction. This condition has been called stress hyper-reflexia. Stress incontinence and hyper-reflexia are 15 easily differentiated. If the leakage stops as soon as the stress is over, it is stress incontinence. If voiding uncontrollably follows the stress, it is hyper-reflexia or detrusor hyperactivity, a common cause especially among the elderly (Campbell's Urology, Ed. P. Walsh et al., 7th Ed., Vol. 1, 1998, p.1023; Raz p. 231).

Among incontinent women in one study, 38% had mixed hyper-reflexia and stress 20 incontinence, and 16.5% had hyper-reflexia alone as the cause of the incontinence (Sand P. K., *Obstet. Gynec.*, 70:57, 1987). As mentioned previously, although genuine stress incontinence is probably the most common cause of urinary incontinence in women, the incidence and prevalence of detrusor hyperactivity increases with age (Bates C. P., *Clin. Obstet. Gynecol.*, 5:109, 1978).

Diagnosis of Urinary Incontinence

25 Physical examination, urodynamics (study of urine propulsion and flow) and cystoscopy (endoscopy for the urinary tract) are commonly used to determine the true nature of the patient's stress incontinence and to guide in the choice of treatment.

To determine urethral hypermobility, a cotton-swab test is used in physical examination. A well-lubricated and sterile cotton-swab is inserted into the urethra. During coughing, an unstable 30 urethra sways and is evident by the outer portion of the cotton swab. If the sway is greater than 15 degrees, the patient has urethral hypermobility.

Cystometry is one of the methods of urodynamics used to measure intravesical bladder pressure during the course of bladder filling. The filling medium may be carbon dioxide or liquid, such as water, saline or radiographic contrast material. Pressure is measured during and after filling (Campbell's Urology, Ed. P. Walsh et al., 7th Ed., Vol. 1, 1998, p.934). With about 200 ml filling medium in the bladder and about 55-cm water pressure, stress is initiated. If voiding stops at the end of the stress, the patient has stress incontinence, which indicates intrinsic sphincter deficiencies (ISD). If voiding continues after the stress ceases, it is likely detrusor hyperactivity, or hyper-reflexia. To determine the degree of incontinence, the fill volume and pressure can be adjusted until involuntary voiding occurs, which is defined as the leak-point pressure in 5 urodynamics.

10

Classification of Stress Incontinence

To evaluate the degree of bladder / urethral support and sphincter competence, stress incontinence is classified into five types. Type 0: Patient complains of stress urinary incontinence. Videourodynamic test reveals that both vesical neck and proximal urethra are closed at rest and 15 situated at or above the lower end of the pubis symphysis. During stress, the vesical neck and proximal urethra descend and open, assuming an anatomic configuration similar to that seen in types I and II stress urinary incontinence, but no urine leaks. Type I: The vesical neck is also closed at rest and situated above the inferior margin of the pubis symphysis. During stress, the vesical neck and proximal urethra open and descend less than 2 cm. Urinary incontinence is 20 apparent with increased abdominal pressure. Type IIA: The vesical neck is also closed at rest and situated above the inferior margin of the pubis symphysis. During stress, the vesical neck and proximal urethra are also open, but with a rotational descent characteristic of a cystourethroccele (prolapse of bladder and urethra) which accompanies urine leakage. Type IIB: The vesical neck is closed at rest but situated at or below the inferior margin of the pubis symphysis. During stress, 25 there may or may not be further decent, but the proximal urethra opens and incontinence ensues. Type III: The bladder neck and urethra are open at rest indicating intrinsic sphincter dysfunction with or without hypermobility. Obvious urinary leakage associated with minimal abdominal pressure or gravity (Campbell's Urology, Ed. P. Walsh et al., 7th Ed., Vol. 1, 1998, pp.1013-1016; Raz S., Female Urology, 2nd Ed., W.B. Saunders Co., 1996, p.345).

30

Non-Surgical Treatments

Non-surgical treatments include (1) pelvic floor exercise to strengthen pelvic muscles, (2) estrogen to thicken mucosa, (3) biofeedback and/or electrical stimulation to stimulate certain sets

of urethral muscles, (4) alpha-sympathomimetic drugs for intrinsic sphincter deficiency, and (5) mechanical devices to clamp the urethra.

Pelvic floor exercise and estrogen may have value as preventive measures.

5 Biofeedback and electrical stimulation have been reported to cause improvement in 30% to 75% of patients; but "cure" is about 10% with few long-term data confirming the claims. Drug therapy has very limited success with significant side effects.

Urethral removable plugs (US patent 5,562,599 to Beyschlag, US patent 4,457,299 to Cornwell, US patent 5,131,906 to Chen, US patent 5,906,575 to Conway et al., US patent 5,885,204 to Vergano) are uncomfortable and troublesome to use, with increased possibility of

10 urinary tract infections. Penile clamping devices (US patent 4,942,886 to Timmons) are also highly uncomfortable, unnatural and may even cut off blood supply. For females, pessary devices (US patent 5,007,894 to Enhoring, US patent 5,386,836 to Biswas, US patent 5,785,640 to Kresch et al.) are designed to be worn in the vagina to compress and stop the leakage of urine. To be effective, the compression has to be strong and uncomfortable. Similar to the urethral plugs, 15 pessary devices are troublesome to use, messy during menstrual periods and increase the possibility of infections.

Surgical Treatment

In general, surgical treatments for urinary incontinence are far more successful than existing non-surgical treatments, and are the only reasonable long-term solution thus far. The 20 primary goals of the surgical approaches for sphincteric incontinence are (1) to correct urethral hypermobility and the excessive anatomic descent of the bladder neck / urethra, and (2) to increase urethral resistance by improving urethral coaptation and compression for treating intrinsic sphincter dysfunction (Campbell's Urology, Ed. P. Walsh et al., 7th Ed., Vol. 1, 1998, p. 1018, p.1066). Surgical procedures designed to meet these two simple goals differ in their suture 25 material, placement, depth, distance from urethra and location of abdominal anchoring sites.

For anatomic corrections, sutures are used to pull and lift the vaginal wall forward and upward along with the urethra and bladder neck. In essence, the vaginal tissue serves as the supporting backboard for the urethra. Sutures are then fastened onto abdominal tissue or the pubis symphysis. The major differences between surgical procedures of this type are the location 30 of incisions, vaginal suspension, transvaginal suspension, and requirement of tissue dissection.

Burch and Marshal-Marchetti-Krantz procedures use the vaginal-abdominal approach requiring abdominal incisions; while Raz suspensions, Stamey needle and Gittes needle are the

transvaginal suspension procedures. Some surgeons prefer opening both abdominal and vaginal cavities.

Several less invasive needles and devices (US patent 5,860,425, US patent 5,836,314 to Benderev et al., US patent 5,816,258 to Jervis, US patent 5,697,931 to Thompson, US patent 5,647,836 to Blake and US patent 5,549,617 to Green et al.) are designed to pull the urethra forward by attaching and pulling the vaginal wall. Without a direct view of the surgical site, one of the major potential problems with the devices is the uncertainty of suture tension, let alone obtaining the optimal suture tension. If the suture is too tight, the urethra is too restricted, and urinary obstruction occurs. Removing existing sutures with surrounding fibrotic tissue formation 10 is an invasive surgery. If the tension is too loose, incontinence continues.

Common anatomic surgical complications include recurrent or persistent urinary incontinence, irritation, urinary retention, obstruction and/or persistent postoperative pain, which may be caused by urethral kinking, improper suture placement or improper tension. Other complications, such as wound infection, abscess formation, genitofemoral nerve entrapment, 15 bladder leaks or urethral damages, are common occurrences as well (Campbell's Urology, Ed. P. Walsh et al., 7th Ed., Vol. 1, 1998, p.1100). The overall complication rate ranges from 3% to 32% (Campbell's Urology, Ed. P. Walsh et al., 7th Ed., Vol. 1, 1998, p.1101). Furthermore, due to depth and axis alteration, numerous vaginal posterior prolapses have been reported following anatomic correction (Langer R. et al., Obstet. Gynecol. 1988, 72:866-869; Wiskind A. K., et al., 20 Am. J. Obstet. Gynecol., 1992: 167:399-405; Campbell's Urology, Ed. P. Walsh et al., 7th Ed., Vol. 1, 1998, p.1101).

For intrinsic sphincter dysfunction, merely anatomic correction supported by a soft vaginal tissue is inadequate. Sling procedures are designed to loop behind the urethra and fasten onto the abdominal tissue. The loop forms a backboard, which compresses and restricts the urethral 25 sphincter. Slings are also effective on neurogenic intrinsic sphincter deficiency, such as myelodysplasia, a defective development of the lower segment of the spinal cord. (Gormley E. A., J. Urol. 1994, 152:822; McGuire E. J., J. Urol., 1987, 138:525-526; McGuire E. J., J. Urol., 1986, 135:94). A less invasive sling needle (US patent 5,899,909 to Claren et al.) has been invented to treat female sphincteric deficiency.

30 Various sling materials, including autologous, heterologous, or artificial materials, have been used. One invention (US patent 5,934,283 to Willem et al.) utilizes non-suture material as a sling.

Common complications of the slings include sensations of inguinal pulling, potential erosion of the urethra, urinary retention, urethral obstruction and enterocele (posterior vaginal hernia). Most of these complications are once again due to improper tension of the suture or sling. If the sling is too tight, the urethra is obstructed; if it is too loose, incontinence continues.

5 Unfortunately, no standard parameters exist to identify the appropriate degree of sling tension. Thus, it remains more an art than a science, with a limited margin of error.

Two other techniques, injectable materials and artificial sphincters, are often used to treat intrinsic sphincter deficiency. Injectable or bulking agents, such as collagen, polytetrafluoroethylene (PTFE), autologous fat and silicone, are injected into the wall of the

10 bladder neck or urethral mucosa to decrease the size of the lumen opening to provide a more manageable or controllable sphincter. However, multiple injections are usually necessary for achieving some improvement, especially in males. Furthermore, all these bulking agents migrate or metabolize away, some in less than a few months. Collagen begins degradation in twelve weeks. PTFE migrates and granuloma forms (Malizia A. A. Jr., et al., JAMA 1984, 251:3277-3281).

15 Silicone polymers migrate and deposit in the lungs, kidneys, brain and lymph nodes.

Usually when all else fails in treating intrinsic sphincter deficiency, an artificial sphincter is implanted beneath the bladder neck around the urethra, mechanically pinching or restricting the opening of the lumen. Numerous artificial sphincters (US patent 5,893,826 to Salama, US patent 5,704,893 to Timm, US patent 5,562,598 to Whalen et al., US patent 5,097,848 to Schwarz, US patent 4,994,020 to Polyak, US patent 4,705,518 to Baker et al., US patent 4,632,114 to Todd et al. and US patent 4,552,128 to Haber) are designed to restrict the urethra mechanically.

20 Implantation of an artificial sphincter is an invasive surgery. Typically, an inflatable cuff is inserted around the bulbous urethra in the male or the bladder neck in the female. The tubing, liquid reservoir and pumps are implanted in the abdomen. Hospital post-surgical care is around three days.

25 Post-surgical complications include hematoma, cuff erosion, tissue atrophy, early infection from surgical contamination, late infection from urinary tract origin and mechanical malfunction such as tube kinking or leaks (Carson C. C., Urol. Clin. North. Am., 1989, 16:139-147). Tissue atrophy is a natural result of cuff compression over time, which is often followed by cuff erosion with symptoms of pain, swelling, infection and/or bloody discharge. Confirmation of erosion mandates cuff removal (Campbell's Urology, Ed. P. Walsh et al., 7th Ed., Vol. 1, 1998, p.1131-1132).

To maximize the longevity of the artificial sphincter, multiple life-long restrictions are imposed, including deactivation of the sphincter as often as possible, avoiding bicycle riding, horseback riding and prolonged sitting. Furthermore, during pregnancies, the sphincter needs to be deactivated during the last trimester; then delivery by cesarean section is strongly recommended

5 (Barrett D. M., et al., Urol. Clin. North. Am., 1989, 16:119-132; Campbell's Urology, Ed. P. Walsh et al., 7th Ed., Vol. 1, 1998, p.1111 and p.1130-1131).

Urethral Obstruction

One of the most common urinary dysfunctions among middle aged and elderly men is urethral obstruction; and the most common cause of the obstruction is lumen narrowing of the

10 supple urethra by an enlarged prostate called benign prostatic hyperplasia (BPH). Two classes of drugs are available to ease the urethral blockage. Alpha-blockers, such as phenoxybenzamine, prazosin, terazosin and doxazosin, are used to relax smooth muscles such as the one around the prostate, thus minimizing the restriction around the urethra. However, alpha-blockers have the side effect of hypotension, characterized by dizziness. From the androgen suppression class,

15 Finasteride is the only drug with clinically acceptable tolerance. Androgen suppression causes a reduction in prostate volume, hence reducing the obstruction around the urethra. The primary side effect to androgen suppression is impotence and decreased ejaculatory volume.

Many minimally invasive treatments, including high intensity ultrasound, laser, hyperthermia, thermotherapy, electro-vaporization, radio-frequency ablation, stents and balloon

20 dilation, have been invented for BPH. However, surgical transurethral resection of the prostate has been and still is the gold standard in terms of improving flow rate and decreasing postvoid residual urine.

SUMMARY OF INVENTIONS

25 Similar to the primary goals of the backboard surgical procedures, this invention also corrects urethral hypermobility by providing posterior support and treats intrinsic sphincter dysfunction by increasing urethral resistance. Instead of relying on repositioning tissues to gain support through significantly invasive procedures, an internal urethral support is inserted through and anchored within the urethra to promote urethral closure from inside of the urethra, non-

30 invasively. Another part of this invention restricts or partially ligates the openings of the bladder neck and/or urethra through a minimally invasive suturing technique. For urethral obstruction, a

similar internal urethral support is used within the urethra to stretch, stiffen and widen the urethral lumen against the obstruction.

Internal Urethral Support

For ease of urethral insertion, a portion of an internal urethral support can be made with resilient material capable of bending or folding. In the bent or closed configuration, one or more internal urethral support(s) is / are fitted into a delivery device to be delivered into the urethra. The closed position of the internal urethral support can also be called the delivery position. To promote urethral closure, the internal urethral support is best deployed and opened in the urethra laterally. In the deployed position, the urethral support is in a stable and relaxed configuration. If the internal urethral support is deployed near the center of the urethra, the tension of the urethral wall is overcome by the stretching and straightening of the internal urethral support. The urethra is laterally stretched from a round to an elliptical shape, bringing the anterior and posterior walls closer together. Because of the pre-disposed shape and pre-stretched urethra, the forces required by the urethropelvic ligament to close the lumen of the urethra become less demanding during abdominal stress, such as sneezing or coughing.

During lumen closure, the internal urethral support is hidden and buried in the resiliently spongy and supple lining of the coaptated mucosa of the anterior and posterior urethral walls. Furthermore, since the deployed internal urethral support causes the urethral wall to be stretched and stiffened under its tension, the muscle-poor posterior wall is less likely to move away from the compression of the muscle-rich anterior urethral wall during stress.

To add more support to the posterior wall, the internal urethral support can be selectively deployed toward the posterior wall inside the urethra. The deployed internal urethral support stretches, stiffens and may even flatten a section of the urethral posterior wall to keep it from retreating during stress. The muscle-poor posterior wall essentially remains stationary relative to the muscle-rich anterior wall, allowing a firm anterior compression to seal the lumen and prevent leakage during stress.

Multiple internal urethral supports can be individually deployed into a section of urethra to pre-stretch and pre-dispose the urethral wall, and at the same time to support a greater section of urethral posterior wall from inside and thus greatly enhance sphincteric action. Since each internal urethral support operates independently, the normal movements of urethra, including its lengthwise compression and extension, crucial for voiding and urinary control, should not be interfered with by multiple internal urethral support deployments.

Resting Sphincteric Closure by Internal Urethral Support as Urethral Anchors

Some patients, including those with the Type III stress incontinence, suffer from an opened urethra at rest, with the possibility of constant leakage even without stress. To increase urethral resistance, a sphincteric shaper made with a curved or shape memory rod anchored by two or

5 more internal urethral supports is embedded in the outwardly sagging posterior urethral wall. In the urethra, the shape memory rod resumes the pre-disposed curvature, pulling the posterior wall toward the anterior wall to narrow or close the lumen.

During voluntary voiding with the sphincteric shaper, the detrusor muscle and voluntary urethral muscle shorten and widen the urethra to overcome the device-induced closure, similar to 10 the voluntary opening of the urethra following injection with large amounts of bulking agents, such as collagen.

Due to the supple nature of the urethra, it is also possible to close the opened lumen by magnetic forces. One or more magnets is / are mounted on an internal urethral support. One magnetic internal urethral support is installed in the posterior urethral wall; and another magnetic 15 internal urethral support is installed in the anterior urethral wall across from it. In essence, the magnets are mounted within the mucosa, approximating the posterior and anterior walls and closing the lumen. During voluntary voiding, the detrusor muscles and voluntary urethral muscles shorten and widen the urethra to overcome the magnetically induced closure.

As mentioned, generally the controlling motions of the urethral sphincter are (1) shortening 20 and widening the lumen to void, and (2) extending and narrowing the lumen to interrupt. A urethral extensor comprised of two internal urethral supports acting as urethral anchors linked by a connector is designed to mimic the extension of the urethra. The internal urethral supports are spring loaded, designed to pull the two internal urethral supports apart within the urethra. In response to the lengthwise stretching of the urethra by the anchored internal urethral supports in 25 the lumen, the urethra lengthens and the opening of the lumen is narrowed and restricted during resting. For voluntary voiding, the detrusor muscle and voluntary urethral muscle shorten and widen the urethra to overcome the device-induced closure.

Other Types of Internal Urethral Support

In addition to bending the internal urethral support into a closed or delivery position, for 30 ease of insertion and implantation, the opened and closed positions of the internal urethral support can be controlled by spring, hinge or multiple resilient elements. In the urethra, the opened position of the internal urethral support can also be called the deployed position. It may even be

possible to insert a rigid internal urethral support in the urethra by manipulation into a deployed position within the urethra, without bending or folding the device. The internal urethral support can be made with biodegradable material, modular components, flexible and/or rigid portions.

5 To prevent migration of the internal urethral support with time, tissue ingrowth openings can be made in the internal urethral support device, especially around mucosal contacts.

Benefits of Internal Urethral Support Over Surgical Procedures

Instead of relying on repositioning tissues to provide support through significantly invasive procedures, the internal urethral support is inserted into the urethra non-invasively to pre-stretch the wall, pre-dispose the urethra, support and/or stiffen the posterior wall for closure. For intrinsic 10 urethral deficiency, slings, injectables and artificial sphincters are presently being used to increase urethral resistance. Internal urethra supports can also be used in multiple variations to promote urethral closure non-invasively: (1) to connect with a shape memory element bringing the posterior wall forward, (2) to pull the urethral walls together by magnets, or (3) to lengthen the urethra and collapse the lumen by tensile forces.

15 Non-invasive procedures usually translate into significantly lower costs, much shorter recovery times, far fewer complications, and are much more suitable to elderly or weak patients. Furthermore, these non-invasive inventions may apply to men, women, and childbearing women, with minimal to no lifestyle restrictions.

Partial Ligation of Bladder Neck and Urethra

20 Artificial sphincter and sling procedures, prior arts, are designed to increase urethral resistance, particularly helpful for patients with intrinsic sphincter deficiency. The most hazardous and painstaking part of the procedure is the dissection behind the bladder neck or delicate urethra. During the dissection, the bladder or urethra is frequently cut or punctured, requiring repair and postponement of the surgical procedure until the puncture has healed. A suture device (US Patent 25 5,895,395 to Yeung) is designed to guide a suture behind a structure such as the bladder neck or urethra through a small abdominal incision, without dissection.

30 Among past surgical failures in various bladder and urethra repositioning procedures, many sutures approximating the urethra to the abdominal ligaments were too close to the urethra. Due to the close proximity of the suture and the pliable nature of the urethra, the tension of the suture created kinks in the urethra, causing urinary obstruction. Furthermore, the rubbing of the abdominally anchored suture onto the urethra is presumably the cause of fibrotic tissue formation

around the urethra and sometimes urethral erosion to the point of severance. Surgeons everywhere are taught to avoid suturing near the urethra to correct incontinence.

The partial bladder neck or partial urethral ligation procedure proposed in this invention is different. The suture is used only to restrict the lumen opening and support the urethral wall by 5 encircling and being tied around the bladder neck or urethra, without attaching to abdominal tissue. Therefore, the suture is under minimal tension and rubbing friction around the bladder neck or urethra. To prevent excessive lumen restriction by the ligating suture, a spacer shaped and sized to provide a manageable lumen opening is inserted from the urethra into the bladder. With the partially restricted urine passages, the patient requires less muscular movement and intensity to 10 close the partially restricted lumen, resulting in improved urinary control.

Acknowledged by experts, suture tension for anatomic correction or sling procedures is more of an art than a science. Most complications are caused by excessive or inadequate suture tension. On the other hand, the conforming spacer within the urethra limits the suture tying to a partial ligation. Unlike the vaginal sling procedure, partial ligation does not involve the vagina. 15 Therefore, it is acceptable to men and childbearing women as well. Unlike the bulky, tissue choking cuff of an artificial sphincter, the size and tension of the suture and external urethral support in partial ligation are insignificant; hence little to no lifestyle restrictions are imposed. With an endoscopic suture device, partial ligation is a minimally invasive procedure, yet it has the potential benefits of the invasive procedures without as many potential complications, lengthy 20 recovery time and multiple life restrictions.

Opening Urethral Obstruction with Internal Urethral Support

Many minimally invasive devices have been approved by the US FDA. Urethral stents, the only non-invasive device, are used to open the restricted urethra around the benign prostatic hyperplasia. However, given time, epithelial tissues penetrate into the lumen of the stents, which 25 then require removal.

The internal urethral supports mentioned thus far for urethral closure can additionally be used to open the restricted urethra. Utilizing different internal urethral support orientations within the obstructed urethra, the compressed urethral wall can be stretched and shaped by one or multiple internal urethral support(s) to dilate the lumen and increase urine flow.

30

REFERENCE NUMBERS

| | |
|------------------------|----|
| Suture delivery needle | 1 |
| | 13 |

| | |
|---|-----|
| Suture delivery needle distal opening | 2 |
| Strain, stress relief window | 5 |
| Shape memory needle | 7 |
| Shape memory needle distal opening | 8 |
| 5 Suture receiving needle | 10 |
| Suture receiving needle distal opening | 11 |
| Receiving slot for shape memory needle | 12 |
| Penetration marker | 13 |
| Suture | 21 |
| 10 Filament | 22 |
| Knot pusher | 26 |
| Lumen | 100 |
| Urethra | 101 |
| Direction of urethropelvic ligament tension | 102 |
| 15 Force of urethral closure | 103 |
| Internal urethral support (IUS) | 104 |
| Tissue anchoring element | 105 |
| Resilient element | 106 |
| IUS delivery device | 107 |
| 20 Flexible plunger | 108 |
| Flexible tube | 109 |
| Deploy opening | 110 |
| Bladder | 111 |
| Bladder neck | 112 |
| 25 Mucosa | 113 |
| Vagina | 114 |
| Pubis symphysis | 115 |
| Rectum | 116 |
| Urine | 117 |
| 30 Anterior urethral wall | 118 |
| Posterior urethral wall | 119 |
| IUS delivery device insertion marker | 120 |

| | |
|--------------------------------------|-----|
| Suture knot | 121 |
| Penetration stops | 122 |
| Tissue ingrowth opening | 123 |
| Prostate | 124 |
| 5 IUS hinge | 125 |
| Pad | 126 |
| External urethral support | 127 |
| Spacer | 128 |
| Spacer insertion marker | 129 |
| 10 Spacer orientation line | 130 |
| Lateral urethral wall | 131 |
| Spacer opening | 132 |
| Spacer posterior wall | 133 |
| Urethral check-valve | 134 |
| 15 Bladder filling medium | 135 |
| Reservoir check-valve | 136 |
| Syringe | 137 |
| Pressure gauge | 138 |
| Three-way valve | 139 |
| 20 Drain | 140 |
| Luer lock connector | 141 |
| Spring | 142 |
| IUS delivery device orientation line | 143 |
| IUS connector | 144 |
| 25 IUS connection port | 145 |
| Sphincteric shaper elastic rod | 146 |
| Detrusor contraction | 147 |
| End cap | 148 |
| IUS separator | 149 |
| 30 Medium reservoir | 150 |
| Spring retainer | 151 |
| Sphincteric shaper | 152 |

| | |
|----------------------------------|-----|
| Urethral extensor | 153 |
| Suture device | 154 |
| Magnet | 155 |
| Magnetic urethral closure device | 156 |

5

BRIEF DESCRIPTION OF DRAWINGS

Figure 1 depicts a section of a well-supported urethra 101 with a thick layer of resilient mucosa 113 and a lumen 100 opening.

Figure 2 shows the well-supported urethra 101 under stress with the urethropelvic ligament 102 pulling the lateral walls 131 of the supple urethra 101 to pinch the lumen 100 shut.

Figure 3 indicates bladder 111 positions: a well-supported position in dashed lines and a descended position with a widened bladder neck 112 in solid lines.

Figure 4 depicts a section of poorly supported, leaning urethra 101.

Figure 5 shows a failed attempt of lumen 100 closure and hypermobility of the poorly supported urethra 101 during stress.

Figure 6 depicts a longitudinal section of the urethra 101 with urethropelvic ligaments located perpendicularly above and below the page.

Figure 7 indicates a longitudinal view of urine 117 leakage from a weakened or poorly supported urethral posterior wall 119 during stress.

Figure 8 shows a typical prior art surgical procedure for urinary incontinence, using sutures 21 to pull the vagina 114 forward, supporting or gently compressing the urethral posterior wall.

Figure 9 depicts a section of the surgically corrected urethra 101 with sutures 21 pulling the vaginal 114 tissue to support and gently compress the urethral posterior wall 119.

Figure 10 shows the lumen 100 closure of the surgically corrected urethra 101 under stress with urethropelvic ligaments 102 pulling the lateral walls 131 of the supported urethra 101.

Figure 11 shows an internal urethral support (IUS) 104 with a resilient element 106, tissue-anchoring elements 105, and penetration stops 122.

Figure 12 depicts a resiliently bent internal urethral support 104, similar to the one in Figure 11.

Figure 13 depicts an IUS delivery device 107 marked with insertion markers 120 and orientation line 143 and loaded with a resiliently bent internal urethral support 104.

Figure 14 shows the insertion of the IUS delivery device 107 and deployment of the internal urethral support 104 into the lumen 100 of the urethra 101.

Figure 15 depicts a deployed internal urethral support 104 resiliently straightened in the urethra 101, laterally extended to pre-dispose the shape and direction of the lumen 100 closure 5 during stress.

Figure 16 indicates a section of the poorly supported urethra 101 with the resiliently straightened internal urethral support 104 pre-stretching and breaking the wall tension to pre-dispose the shape and enhance lumen 100 closure.

Figure 17 shows the ease of lumen 100 closure during stress when assisted by the wall-10 tension breaking and shape altering internal urethral support 104 hidden in the spongy mucosa 113.

Figure 18 depicts another IUS delivery device 107 with the deployment opening 110 off-centered for reaching a different quadrant of the urethra 101.

Figure 19 shows yet another IUS delivery device 107 with the internal urethral support 104 15 slanted or positioned for deploying the internal urethral support 104 toward one side of the urethra 101.

Figure 20 indicates a cross-section of a urethra 101 with an internal urethral support 104 partially embedded in the mucosa, stretching and stiffening the posterior wall 119.

Figure 21 shows two internal urethral supports 104 supporting and strengthening a section 20 of the posterior wall 119, without interfering with the normal urethral movements of lengthwise compression and extension.

Figure 22 indicates a restored lumen 100 stress closure by creating a backboard with internal urethral supports 104, stretching and stiffening the posterior wall 119.

Figure 23 depicts a longitudinal view of a poorly supported urethra 101 with an internal 25 urethral support 104 embedded in the spongy mucosa 113 of the posterior wall 119.

Figure 24 shows lumen 100 closure during stress with an internal urethral support 104 supporting the urethral posterior wall 119, the urethropelvic ligaments pulling perpendicular to the page.

Figure 25 indicates a cross-section of urethra 101 with a thick layer of mucosa 113 and an 30 open lumen 100.

Figure 26 shows a normal lumen 100 closure during stress, initiated by the pulling of urethropelvic ligaments 102, with closure distances A and B.

Figure 27 depicts a cross-section of an inadequate lumen 100 closure of a poorly supported urethra 101 during stress, where the closure distance b of the posterior wall 119 is inadequate.

Figure 28 indicates a cross-section of a poorly supported urethra 101 with the lumen 100 pre-stretched and reshaped by an internal urethral support 104.

5 Figure 29 shows a similar view as Figure 28 during stress, with distance of closure indicated by A' for the anterior wall 118 and B' for the posterior wall 119.

Figure 30 depicts a poorly supported urethra 101 with the lumen 100 pre-stretched by an internal urethral support 104 at the posterior wall 119, providing a supportive structure for a backboard.

10 Figure 31 indicates the lumen 100 closure of Figure 30 during stress, with distance of closure indicated by A'' for the anterior wall 118, and a very small B'' for the posterior wall 119.

Figure 32 shows a possible connection of two or more internal urethral supports 104 by a connector 144, which allows vertical movement and resilient bending of individual internal urethral support 104.

15 Figure 33 depicts an internal urethral support 104 with a connection port 145.

Figure 34 depicts an internal urethral support 104 as in Figure 33 in a bent configuration.

Figure 35 introduces a sphincteric shaper 152 with internal urethral supports 104 linked by a curved elastic rod 146.

20 Figure 36 shows IUS separators 149, which restrict and divide the internal urethral supports 104 during loading into a delivery device and deployment into the urethra.

Figure 37 depicts the lumen 100 closure by indenting the posterior wall 119 inward with the sphincteric shaper 152. The direction of indentation is indicated by the arrow.

Figure 38 shows a longitudinal view of the lumen 100 closure by the curvature of the embedded sphincteric shaper 152.

25 Figure 39 depicts a similar view as Figure 38 during voiding with detrusor contraction 147, indicated by the arrows, which shortens and widens the urethra 101.

Figure 40 shows a spring-loaded pair of internal urethral supports 104 in a urethral extensor 153 device, where the springs 142 are stretched under tension.

Figure 41 depicts a similar device as the one in Figure 40 with a pair of spring retainers 151 30 to keep the springs 142 under tension during implantation.

Figure 42 depicts two contracting springs 142 pulling two internal urethral supports 142 further apart.

Figure 43 shows the urethral extensor 153 with the spring retainers 151 inserted into a urethra 101.

Figure 44 depicts tensile stretching of the urethra 101 by the urethral extensor 153 to mimic normal urethral closure, indicated by lumen 100 closure in dashed lines.

5 Figure 45 shows a longitudinal view of a stretch-induced lumen 100 closure by the urethral extensor 153 device at rest.

Figure 46 depicts a deployed or opened position of another version of an internal urethral support 104, which extends by a spring 142.

10 Figure 47 shows a compressed or closed position of the internal urethral support 104 indicated in Figure 46.

Figure 48 depicts another type of internal urethral support 104 with locking hinge 125 in an opened or deployed position.

Figure 49 shows a partially folded internal urethral support 104 for urethral insertion.

15 Figure 50 indicates an internal urethral support 104 with two resilient elements 106 held by two end caps 148, in an opened or deployed position.

Figure 51 shows a compressed or closed configuration of the internal urethral support 104 shown in Figure 50.

Figure 52 depicts a rigid internal urethral support 104 with smooth contour for installation in urethra, and tissue ingrowth openings 123 for anchoring and prevention of migration.

20 Figure 53 depicts another type of internal urethral support 104 with multiple tissue anchoring elements 105 and a resilient element 106, in an opened or deployed position.

Figure 54 shows a resiliently bent internal urethral support 104, similar to the one in Figure 53.

25 Figure 55 indicates an IUS delivery device 107 loaded with an internal urethral support 104.

Figure 56 shows a surgical approach to narrowing the enlarged opening of the bladder neck 112 and to gently compress the urethral sphincter by a suture 21 sling.

Figure 57 indicates an endoscopic suture device 154 containing a suture delivery needle 1, shape memory needle 7, and suture receiving needle 10.

30 Figure 58 depicts the deployed hook of the shape memory needle 7, bridging the gap between suture delivery needle 1 and suture receiving needle 10.

Figure 59 shows a spacer 128 sized to provide a manageable opening for bladder neck and/or urethra during the partial ligation procedure.

Figure 60 depicts an abdominal penetration of the suture device 154 straddling the bladder neck 112 with a spacer 128 inserted. The shape memory needle 7 contains a flexible filament 22.

5 Figure 61 indicates the deployment of the shape memory needle 7 into the distal opening 11 of the suture receiving needle 10 behind the bladder neck 112.

Figure 62 shows the advancement of the filament 22 by pushing the filament 22 into the proximal opening of shape memory needle 7, exiting the proximal opening of the suture receiving needle 10.

10 Figure 63 depicts retraction of the resilient hook of shape memory needle 7 back into the suture delivery needle 1, leaving only the suture 21 behind the bladder neck 112.

Figure 64 shows the withdrawal of the suture device 154, suture delivery needle 1 and suture receiving needle 10, leaving the suture 21 looped behind the bladder neck 112.

15 Figure 65 depicts lumen 100 restriction by a suture 21 tied with a knot pusher 21. The spacer 128 in the bladder neck 112 prevents excessive closure, which could lead to urine retention.

Figure 66 shows a semi-rigid external support 127 advancing behind the bladder neck 112, by the connecting suture 21.

Figure 67 indicates a partial ligation with the external support 127 tied behind the bladder neck 112, with a final lumen 100 opening sized by the withdrawn spacer.

20 Figure 68 depicts multiple partial ligations along the urethra 101 and around the bladder neck 112 with the external supports 127 strengthening the posterior wall 119.

Figure 69A shows another version of spacer 128 with two sizes and shapes for maximizing the efficacy of partial ligations.

25 Figure 69B indicates a spacer 128 with a large cylindrical distal end, specially designed to partially ligate the lumen 100 in the bladder neck 112.

Figure 70 shows a spacer 128 connected to a bladder filling and pressure checking instrument.

Figure 71 indicates the combination of partial ligation to limit the size of lumen 100 and multiple internal urethral supports 104 to support the urethra 101, without interfering with normal urethral movements.

30 Figure 72 depicts the compression of lateral urethral walls 131, greatly restricting the lumen 100 opening by benign prostatic hyperplasia.

Figure 73 shows the lumen 100 enlarged by the deployed internal urethral supports 104, stretching and stiffening the urethral walls.

Figure 74 indicates another lumen 100 enlargement by the deployed internal urethral supports 104, pushing out the lateral urethral walls 131 above and anterior 118 and posterior 119 walls below.

Figure 75 depicts a modular internal urethral support 104 with a resilient element 106, a tissue anchoring element 105 and a tissue ingrowth opening 123, composed of multiple pieces.

Figure 76 shows a magnetic urethral closure device 156 made with a pair of magnetic internal urethral supports 104.

Figure 77 indicates the attractive forces of the magnets 155 drawing the pair of internal urethral supports 104 close to each other.

Figure 78 depicts a urethral lumen 100 closure activated by magnetic attraction from the magnetic urethral closure device 156.

Figure 79 shows the opening of the lumen 100 from detrusor contraction, indicated by arrows, overcoming the magnetic forces of the magnetic urethral closure device 156.

Figure 80 indicates three types of tissue anchoring elements, a tissue-penetrating spear, a tissue hook and a tissue ingrowth opening 123.

DETAILED DESCRIPTION OF THE EMBODIMENTS

Figure 1 depicts a section of a well-supported urethra 101 with a thick layer of resilient mucosa 113 and a lumen 100 opening.

Figure 2 shows the well-supported urethra 101 under stress with the urethropelvic ligament 102 pulling the lateral walls 131 of the supple urethra 101 to pinch the lumen 100 shut.

The traditional prior art surgical treatment for urinary incontinence is to support the urethral posterior wall 119, usually by repositioning the vagina 114 with sutures 21. The vaginal repositioning in Figure 8 indicates the pre-surgical positions of the vagina 114 in dotted lines and the urethra 101 and bladder in dashed lines. Figure 9 indicates the posterior wall 119 support in a section of the urethra 101. This significantly invasive procedure provides the backboard support needed for the urethral sphincteric closure during stress as shown in Figure 10.

Instead of invasively placing a support outside the urethra 101, the internal urethral support (IUS) 104, shown in Figure 11, is a non-invasive or micro-invasive insert, entering through the external opening of the urethra 101 to anchor within the urethra 101.

Several principles behind using the internal urethral support 104 to treat incontinence are (1) breaking the tension of the lateral urethral wall 131 by pre-stretching the urethra 101 from inside, (2) narrowing the lumen 100 by approximating the posterior 119 and anterior 118 walls toward closure, and/or (3) supporting and stiffening the posterior wall 119 for compression

5 closure of the muscle-rich anterior wall 118 during stress. To make these missions possible and practical, the internal urethral support 104 must be stiff enough to stretch out the urethral wall 131, anchor well without shifting, be thin enough to allow mucosal 113 coaptation, and be biocompatible with the urethra 101.

For constructing the internal urethral support 104, numerous materials, including plastics 10 and metals, are adequately stiff to stretch the supple urethra 101, but not many can be bent from an open or deployed position as in Figure 11 to a closed or delivery position as in Figure 12. Shape memory alloys, such as nickel titanium, and some polymers, such as polypropylene, polyethylene and polytetrafluoroethylene, have the elastic modulus to tolerate bending as well as the stiffness to perform. Other types of internal urethral supports 104, indicated in Figures 46 to 52, do not 15 require such vigorous bending for delivery.

The spring 142 loaded internal urethral support 104 can extend nearly twice the length from a delivery position as indicated in Figure 47 to a deployed position in Figure 46. The internal urethral support 104 can also be operated by a hinge 125 between two projecting members. In the delivery position, the internal urethral support 104 is folded, as depicted in Figure 49. Within the 20 urethra 101, the projecting member will then be deployed, as indicated in Figure 48. The deployed position can be locked by a locking hinge 125 to ensure proper anchoring within the urethra 101.

Due to the normal muscular movement of the urethra 101, the fluid dynamics of urine and the importance of internal urethral support 104 location, anchoring of the internal urethral support 104 is crucial for long term success. In Figure 11, two spike-like tissue anchoring elements or 25 projections 105 protruding from both ends are designed to pass through the mucosa 113 and to anchor in the urethral muscle beneath, while smooth surfaced penetration stops 122 compress the spongy mucosa 113 and rest on the surface of the urethral muscle, the external layer of urethra 101, indicated in Figure 16. Figure 15 depicts a longitudinal view of urethral stretching, shaping and/or widening by the deployed internal urethral support 104. For long term anchoring, tissue 30 ingrowth openings 123 as indicated in Figure 52 promote incorporation of tissue into the internal urethral support 104 to prevent device migration. This style of internal urethral support 104 may be formed of a generally rigid material and manipulated into a deployed position within the urethra,

without bending or folding the device. It is also possible to have both tissue ingrowth opening 123 and tissue anchoring elements 105 in an internal urethral support 104 as indicated in Figure 80. Figure 53 shows variation of the internal urethral support 104 in a deployed position, Figure 54 in a delivery position and Figure 55 within a delivery device 107. This version of the internal urethral 5 support has a series of hook-like tissue anchoring elements 105 designed to anchor onto the mucosa 113.

Due to the set direction of lumen 100 closure controlled by the urethral muscles and urethropelvic ligament, the orientation and position of the internal urethral support 104 are crucial to promote continence. The urethral 101 sphincter consists of bundles of circularly arranged 10 muscular fibers with maximal density in the anterior section, thinning laterally and being almost totally deficient posteriorly. Research indicates that during stress on a poorly supported urethra 101 depicted in Figures 3 and 4, an unequal movement of the muscular anterior 118 and muscle 15 deficient posterior 119 walls appears, resulting in retreat of the posterior wall 119, depicted in Figures 5. Thus, leakage occurs, as indicated in Figure 7. To promote lumen 100 closure in the present invention, the urethra 101 is pre-stretched laterally by the internal urethral support 104 along the direction of closure when stressed. The deployed internal urethral support 104 serves 15 two major functions, (1) breaking the tension of urethral wall for easy closure, as indicated in Figures 14 to 17, and/or (2) stiffening the urethral wall to prevent retreat.

Figure 13 shows a delivery device 107 loaded with an internal urethral support 104 for 20 urethral insertion. Figure 14 shows the delivery device 107 in the urethra 101. A flexible tube 109 and a flexible plunger 108 are made to tolerate the curvature of the urethra 101 during insertion. The insertion marker 120 located on the exterior of the delivery device 107 allows the surgeon to estimate the inserted depth of delivery device 107. For ultrasound guiding capability, the delivery device 107 can be coated or made with echogenic material. For X-ray guiding, a radiopaque 25 coating or material can be used. Since lateral deployment of the internal urethral support 104 across the urethra 101 is preferred, an orientation line 143 is drawn on the device 107 to confirm the lateral position of the internal urethral support 104 prior to deployment. For deployment, the plunger 108 pushes the resiliently closed internal urethral support 104 out of the deploy opening 110, projecting both ends of the internal urethral support 104 outward into the mucosal 113 wall 30 as indicated in Figure 15.

A centered deploy opening 110 at the distal end as shown in Figure 13 provides deployment of the internal urethral support 104 near the center of the urethra 101, pre-stretching

the lateral wall 131 as indicated in Figures 15 and 16. With the reduction of tension around the lateral urethral wall 131, the lumen 100 is more compliant to close or collapse by the tensile contraction of the urethropelvic ligament 102 during stress, as depicted in Figure 17. The thin resilient element 106 of the internal urethral support 104 is concealed by the coaptation of the soft 5 and spongy mucosa 113, the interior layer of urethra 101.

To deliver an internal urethral support 104 near the posterior urethral wall 119, the deploy opening 110 can be shifted from the center to the side of the distal end as shown in Figure 18. To embed an internal urethral support 104 on the posterior urethral wall 119, the internal urethral support 104 can be placed at an angle in the delivery device 107 as indicated in Figure 19. Figure 10 20 depicts a deployed internal urethral support 104 stretching and supporting the posterior wall 119 with the resilient element 106 mostly hidden or buried in the spongy mucosa 113. Multiple internal urethral supports 104 can be installed within a section of urethra 101 as shown in Figure 21, without interfering with the normal urethral movement crucial for voiding and urinary control. Figure 23 shows the longitudinal view of the internal urethral support 104 supporting the posterior 15 wall 119. With both the reduction of lateral wall 131 tension and the increased backboard support of posterior wall 119, the lumen 100 is prepared for closure during stress as indicated in Figure 22, reducing the retreat and hypermobility of the posterior wall 119. Figure 24 shows the longitudinal view of the lumen 100 stress closure, due to the urethropelvic ligaments 102 (shown in Figure 22) pulling perpendicularly above and below the page, with the backboard supporting internal urethral 20 support 104 embedded in the posterior wall 119.

A cross-sectional view of a normal lumen 100 opening is depicted in Figure 25. In Figure 26 the lumen 100 is closed by the tensile forces of the urethropelvic ligament 102. In a simplified explanation, the urethropelvic tensile forces 102 are transmitted into urethral wall closure forces pulling the anterior wall 118 through distance A, and the posterior wall 119 through distance B for 25 a successful lumen 100 closure. For a poorly supported urethra 101 as indicated in Figure 27, the urethropelvic tensile forces 102 are not well transmitted into closure forces for the posterior wall 119, which pulls only a small distance b. As a result, leakage occurs. Figure 28 depicts a poorly supported urethra 101 pre-stretched and pre-shaped by an internal urethral support 104 at the center, breaking lateral 131 wall tension, and at the same time increasing anterior 118 and 30 posterior 119 wall tension. Essentially, the internal urethral support 104 is pre-shaping or reshaping the cross-section of the urethra 101. During stress, the lumen 100 in Figure 29 is closed more easily with shorter wall closure distances than even a normal urethral lumen 100 as in Figure

26, where A' < A for anterior 118 closure and B' < B for posterior 119 closure. Figure 30 depicts an internal urethral support 104 embedded in and firmly supporting and stretching the posterior wall 119 of a poorly supported urethra 101. During stress depicted in Figure 31, the posterior wall 119 remains almost stationary, where B" is very small, holding almost still for the coaptation 5 of the muscle-rich anterior wall 118, and the tensile pulling of the urethropelvic ligament 102.

Currently, many prior art incontinence surgical procedures are performed but fail because of incorrect diagnoses. To minimize the possibility of an ineffective internal urethral support 104 permanently inserted in patients, a test version of internal urethral support 104 made with biodegradable materials, such as poly-lactate (PLA), poly-glycolate (PGA), collagen, elastin or 10 gelatin, can be used in a trial. If the internal urethral support 104 is / are effective in improving urinary incontinence, permanent internal urethral supports 104 made with durable materials will then follow after the test version has degraded. However, if the test version was not effective at the inserted site, other locations may be tested for effective urinary control with another biodegradable internal urethral support 104, or a traditional surgical technique may be pursued.

15 The biodegradable internal urethral supports 104 are non-invasive and temporary in patients. In fact, it can be helpful as a diagnostic tool to determine the cause of incontinence, optimize the position of the permanent internal urethral support 104, and to maximize the success rate of traditional treatments, all with minimal invasiveness.

20 The internal urethral support 104 can also be assembled from modular components, as indicated in Figure 75. For example, nickel-titanium chosen for either super-elastic or shape memory properties can be used in the resilient section 106 in connection with polypropylene or other polymers for the penetration stops 122 contacting the mucosa 113.

25 Terminally sterilizing the internal urethral support 104 and delivery device 107 with autoclave, gamma, E-beam or other sterilizing technique can prevent possible urethral infection. Polymers, such as polyetheretherketone, polysulfone, polyethylene, polypropylene, polycarbonate, 30 polyurethane, polyvinyl chloride, polyimide, delrin polytetrafluoroethylene or others, can tolerate one or more of the sterilization techniques.

30 The internal urethral support 104 can also be coated or blended with lubricants, biocompatible material, anticorrosive, antibiotics, growth factors, hormones, time-release substances, radiopaque, echogenic, radioactive, plasma, tissue sealing, hydrophilic, hydrophobic material or a drug.

The internal urethral support 104 can be removed by cutting with endoscopic scissors and retrieving with forceps if necessary for reasons such as infection, discomfort, ineffectiveness or others. It is also possible to design a removable internal urethral support 104 without cutting.

For the convenience of delivery and/or the possibility of improved efficacy, two internal 5 urethral supports 104 may be linked by a connector 144, as depicted in Figure 32, which allows vertical movement to accommodate the natural mobility of the urethra 101. The connector 144 utilizes a post capable of sliding in a tube. The internal urethral support 104 can also have a connecting port 145 as indicated in Figure 33 for linking with other devices, without interfering with the bending capability, as shown in Figure 34.

10

Shape-Memory Induced Urethral Closure

For patients with constant leakage due to their open urethral 101 sphincters, invasive surgeries using a sling or artificial sphincter are available as long term solutions to increase urethral resistance. The present invention provides a non-invasive alternative, a sphincteric shaper 152 containing a shape memory or elastic rod 146, which can be inserted near the posterior urethral 15 wall 119 and anchored by internal urethral supports 104 as indicated in Figure 37. The shape memory rod 146, three anchoring internal urethral supports 104 and two round end caps 148 to avoid urethral puncture are shown in Figure 35. To prevent shifting of the anchoring internal urethral supports 104 along the shape memory rod 146 during device installation, IUS separators 149 are inserted as indicated in Figure 36. The IUS separators 149 can be made with 20 biodegradable materials, such as PLA or PGA, or with moisture activated disintegrating materials, such as gelatin or collagen. In the urethra 101, the anchored shape memory or elastic rod 146 resumes the pre-disposed curvature, pulling the posterior 119 wall forward to meet the anterior 118 wall, thus narrowing and closing part of the lumen 100 as shown in Figure 37. Figure 38 depicts a longitudinal view of the shape memory induced lumen 100 closure, created by the 25 inwardly indented posterior wall 119 embedded with the internal urethral support 104 anchored elastic rod 146.

To urinate, both detrusor 147 and urethral muscles contract to increase urethral wall tension, shortening and widening the lumen 100, and overcoming the indented distance created by the shape memory rod 146 as indicated in Figure 39. As a result, the lumen 100 opens and urine 30 117 flows. A similar mechanism for lumen opening is observed in a urethra injected with as much as 30 cc or more of bulking agents, such as collagen.

To prevent turning of the shape memory or elastic rod 146 in the urethra 101, the connection port 145 of the internal urethral support 104 is square, as indicated in Figure 33; and, as shown in Figure 35, the shape memory rod 146 is also square. Turning of the shape memory rod 146 in the urethra 101 would decrease the lumen 100 closure capability.

5

Magnetically-Induced Urethral Closure

Due to the close proximity between posterior 118 and anterior 119 urethral walls (the internal urethral diameter is typically 6 mm or less) and the supple nature of the urethra 101, it is possible to close the lumen 100 by magnetic forces. Figure 76 and Figure 77 show the magnetic urethral closure device 156 made with a pair of magnetic internal urethral supports 104 shown 10 apart and magnetically drawn together, respectively. Upon installation of the magnetic urethral closure device 156 in the urethra 101 as indicated in Figure 78, the urethral walls are stretched from within, elongating the cross-section of the urethra 101, placing the posterior 119 and anterior 118 walls even closer to each other, and enhancing the magnetic effect of the device. During voluntary voiding with the magnetic urethral closure device 156, the detrusor muscle and 15 voluntary urethral muscle shorten and widen the urethra 101 to overcome the magnetically induced closure, as indicated in Figure 79.

To prevent corrosion of the magnetic urethral closure device 156, a corrosive resistant coating, such as polytetrafluoroethylene or other material, can be applied.

Extension-Induced Urethral Closure

20 To interrupt urine flow, the urethra 101 naturally extends to narrow and close the lumen 100. To mimic urethral extension, the urethral extensor 153 disclosed herein contains two anchored internal urethral supports 104 mounted within an open urethral sphincter. The two internal urethral supports 104 are under tension to separate from each other, thus pulling and extending the urethra 101 to narrow and close the lumen 100. Figure 40 shows two spring 142 25 loaded internal urethral supports 104, where the tensile forces are indicated by the arrows. Spring retainers 151 are used to keep the springs 142 and the internal urethral supports 104 under tension as depicted in Figure 41; and the whole spring loaded device is installed in the urethra 101 as indicated in Figure 43. The spring retainers 151 can be made with biodegradable materials, such as PLA or PGA, or with moisture activated disintegrating materials, such as gelatin or collagen. 30 After degradation or disintegration of the spring retainers 151, the two internal urethral supports 104 are pulled apart by the springs 142, as indicated in Figure 42. With the device in the urethra 101, the urethra 101 lengthens, narrows and closes the lumen 100 as shown in Figure 44. Figure

45 depicts a longitudinal view of the extension-induced lumen 100 closure with a thin connector 144, in this case a square rod, concealed in the coaptation of mucosa 113.

Partial Ligation of Bladder Neck and Urethra

The sling procedure, a prior art, is designed to loop a suture 21, tissue or other material 5 behind the bladder neck 112 or urethra 101 to gently compress and restrict the outlet. Figure 56 depicts the sling correction from a pre-surgical position in dashed line to a manageable opening at the bladder neck 112. However, as mentioned, the most arduous part of placing an artificial sphincter or a sling is the dissection behind the bladder neck 112 or urethra 101. To protect the integrity of the urethra 101 during dissection, the vaginal 114 cavity is frequently cut opened for 10 suture 21 passage.

The endoscopic suture device 154 in US Patent 5,895,395, which is hereby incorporated by reference, may be helpful to place a suture 21 through a small abdominal incision and around the bladder neck 112 without dissecting around the bladder neck 112 or cutting the vagina 114. Figures 57-64 show the operation of the endoscopic suture device 154, which can be used to 15 improve the sling procedure (prior art) of Figure 56 and/or the partial ligation procedure of Figures 65-68. Major components of the suture device 154 contain three needles operating between two simple needle positions. In a retracted position as indicated in Figure 57, a hollow shape memory needle 7 with a sharp hook is resiliently straightened in a suture delivery needle 1. In a deployed position as indicated in Figure 58, the hook is deployed from the suture delivery 20 needle 1 into a suture retrieving needle 10. The procedure begins with the insertion of a spacer 128 as indicated in Figure 59, through the urethra 101 into the bladder 111. A small abdominal incision is made. In the retracted position, the suture device 154 is guided by an endoscope to penetrate the ligament and to straddle the bladder neck 112 or urethra 101 with the suture delivery needle 1 and suture retrieving needle 10. The suture delivery needle 1 and suture retrieving needle 25 10 can also be inserted separately and independently. A flexible filament 22 connecting tip-to-tip with a suture 21 is threaded through the proximal opening of the shape memory needle 7 to the distal opening, as shown in Figure 60. The resilient hook of the shape memory needle 7 is then deployed from the suture delivery needle 1, penetrating tissue behind the bladder neck 112 or urethra 101 into the suture retrieving needle 10, as depicted in Figure 61. The suture-connecting 30 filament 22 is pushed from the proximal opening of the shape memory needle 7 into the distal opening 11 of the suture retrieving needle 10, as indicated in Figure 62. The suture-connecting filament 22 continues to advance and is retrieved from the proximal opening of the suture

retrieving needle 10. As a result, the mid-portion of the suture 21 loops around the bladder neck 112 and both ends of the suture 21 are exposed outside the incision. The filament 22 is then cut off from the suture 21. The hook is retracted back into the suture delivery needle 1, leaving only the suture 21 looped behind the bladder neck 112, as shown in Figure 63. Then, the suture device 154 5 is withdrawn, as depicted in Figure 64. The suture 21 is tied down to the spacer 128 inside the bladder neck 112 with a knot pusher 26, as shown in Figure 65.

For optimal partial ligations, the urethra 101 may benefit greatly from a firm posterior support, while the bladder neck 112 may gain the most resistance simply by a lightly restricting suture 21 to narrow the funneled outlet intensified by anatomic descent. To strengthen the 10 posterior wall 119, a semi-rigid external urethral support 127 can be linked, guided and tied behind the urethra 101 or bladder neck 112 by the suture 21, as depicted in Figure 66. In Figure 67, the bladder neck 112 is partially ligated, restricting the lumen 100 opening by suture 21, without attaching to the abdominal wall.

To create the optimal shape of the ligated openings, the distal portion of the spacer 128 can 15 be made cylindrical, with diameter between 3 mm to 10 mm, for the bladder neck 112, followed by a flat section 133 at the posterior surface of the spacer 128, as indicated in Figure 69A, to conform to the external urethral support 127 shaping the urethra 101. To distinguish the flat section 133 of the spacer 128 in the urethra 101, an orientation line 130 visible to the surgeon is marked on the spacer 128. For the proper insertion depth of the spacer 128, markers 129 are visible to assist with 20 the insertion procedure. To prevent the spacer 128 from slipping in or out of the urethra 101 during surgery, an inflatable balloon at the distal end of the spacer 128 anchoring in the bladder can be helpful (not shown).

The distal portion of the spacer 128 is the operative area for partial ligation. The operative area is made pinch resistant to ensure proper ligated lumen size. To accommodate urethral 25 insertion, the non-operative part of the spacer 128 is preferred to be flexible.

At various positions along the urethra 101, several partial ligations can be performed to increase urethral resistance. With ligaments enveloped around the urethra 101, the sutures 21 can be sewn onto the ligaments without the possibility of sliding along the urethra 101. Since the partial ligations work independently, the normal urethral vertical movement, for urinary voiding 30 and interruption, should not be interfered with, as shown in Figure 68 with arrows indicating the mobility of the urethra 101.

To vary the partial ligation procedure, the suture 21 can be replaced with another tying element, such as a band or a piece of tissue, to increase the width of partial ligation. The tying element can be tied or fastened with a locking device, rather than a knot pusher.

While the patient is still under anesthesia, checking the sphincteric resistance after the

5 partial ligations is possible at the end of the procedure by using a bladder filling medium 135 and pressure checking instrument 138 connected to the spacer 128, as indicated in Figure 70. The bladder 111 is filled with a medium 135, such as colored saline, through the spacer 128 to about 20 to 50 cm water pressure, usually less than 300 cc. The spacer 128 is then withdrawn from the urethra 101. If the type of anesthesia does not interfere with the involuntary control of the bladder

10 111 and urethral sphincter, no medium 135 leakage indicates a good chance of success with the partial ligations. If leakage appears, more or tighter ligations with a thinner spacer 128 would be beneficial, while the patient is still under anesthesia.

Other Partial Ligation Procedures

Similar methods using partial ligation and a spacer 128 device can be used in supporting

15 and fortifying around the exterior blood vessel wall of an aneurysm. Unlike current treatments using coils or stents to fill inside the ballooning aneurysm, partial ligation with a suture 21 or other material supports the exterior wall without constant blood contact, no device migration within the blood vessel, no blood clotting from coil or stent and no migratable blood clot which can cause strokes or other serious ailments.

20 Partial ligation and/or the spacer 128 device can also be used to restrict the opening of the pylorus to delay stomach emptying for weight loss purposes. Especially with an endoscopic suture device, partial ligation of the pylorus is likely to be much less invasive than the stomach stapling technique currently being used to treat obesity. Furthermore, the partial ligation method is likely to be totally reversible by cutting a suture or a pylorus restricting material.

25 Combination Treatments

Since urinary incontinence is the result of at least one, most likely multiple malfunctions in the urinary system, treating urinary incontinence may take more than one approach. For example, to improve or regain sphincteric control, using the combination of partial ligation to restrict the lumen 100 and reverse the funneling effect of the bladder neck 112, and the internal urethral

30 support 104 to pre-stretch, pre-shape and support the urethral walls for stress closure, may provide a highly effective result, as indicated in Figure 71. The devices in this invention are

designed to work independently and cooperatively with each other and with other treatments as well.

Opening Urethral Obstruction with Internal Urethral Support

The supple texture of smooth muscle and the compliant nature of the urethral wall are

5 crucial elements for successful urethral closure during stress. The hollow and compliant urethra 101 is not made to resist external compression by surrounding tissue ingrowth, such as benign prostatic hyperplasia (BPH). As the prostate 124 grows with time, the lumen 100 opening shrinks, as depicted in Figure 72. Prostate growth is sex hormone dependent. For some patients, the growth leads to urethral obstruction.

10 By manipulating the urethral walls, the internal urethral support 104 can stretch open the urethral wall from within, relocating the surrounding prostatic tissues. The internal urethral support 104 can be selectively deployed to press against an obstructive tissue. Figure 73 shows two sets of internal urethral supports 104, above and below, stretching the anterior 118 and posterior 119 walls, and at the same time adding stiffness to the lateral 131 urethral walls. As a

15 result, the lumen 100 opening is widened to expedite urine flow. Figure 74 depicts two sets of staggering internal urethral supports 104, above and below, but rotated ninety degrees from each other, alternating the stretching and stiffening of anterior 118, posterior 119 and lateral 131 walls, to ensure the widening of the lumen 100 along the obstructed urethra 101. The urethral widening may be equally effective with a single internal urethral support 104 within a section of urethra 101, rather than using a pair or more of internal urethral supports 104.

20

Unlike the hollow stents placed within the lumen, which allow tissue ingrowth resulting in clogging, opening of urethral obstructions with the non-invasive internal urethral support 104 may provide long-lasting clearance within the urethra 101.

Opening Blood Vessel Obstruction with Internal Lumen Support

25 For a lumen other than urethral treatments, the device can be more generally called an internal lumen support. Similar methods and devices used in opening the urinary tract with the internal lumen support can be modified in size and shape to open and support a section of collapsed or clotted blood vessels. Especially for vessels too small for stent, bypass or angioplasty, a simple, small and flexible internal lumen support can adequately open collapsed

30 sections or kinks in blood vessels.

Medical Alert Tags

Most of the devices in this invention are designed to increase urethral resistance by narrowing the lumen 100. In hospitals, health care professionals often insert catheters into the urethra 101 for draining. It is possible that the insertion of catheters, especially 12 French or 5 larger, can dislocate the device or even injure the urethra 101. If the patient has the device, a medical alert tag should be worn.

Overall Device and Method

It should be clear to one skilled in the art that the current embodiments, methods and surgical sites are not the only uses for which the invention may be used. Different materials and 10 designs for the internal urethral support, delivery device, spacer, connector, sphincteric shaper, IUS separator, urethral extensor, spring, spring retainer, hinge, tissue ingrowth opening, suture, band, external urethral support, resilient element, tissue anchoring element, penetration stop, suture device and bladder filling equipment can be substituted and used. The use of this invention is also foreseen to restrict the pylorus for weight loss purposes, to promote closure of the anal 15 sphincter and to open clotted arteries and vessels. Nothing in the preceding description should be taken to limit the scope of the present invention. The full scope of the invention is to be determined by the appended claims.

What is claimed is:

1. An internal lumen support for altering the configuration of a soft hollow, tubular body having a lumen and a wall with a resilient interior surface, said internal lumen support comprising:
 - 4 a body having a first end, a second end and a middle portion,
 - 5 a first projection extending from said first end,
 - 6 and a second projection extending from said second end,
- 7 wherein said internal lumen support has an open position and a closed position,- 8 and wherein, when relaxed, said internal lumen support is in said open position.

1. 2. The internal lumen support of claim 1 wherein at least a portion of said body is formed of a resilient material.

1. 3. The internal lumen support of claim 2 wherein said resilient material is a shape memory alloy.

1. 4. The internal lumen support of claim 2 wherein, in said closed position, said first end and said second end are separated by a first distance and wherein, in said open position, said first end and said second end are separated by a second distance, said second distance being greater than said first distance.

1. 5. The internal lumen support of claim 1 wherein said middle portion of said body is formed of a resilient material.

1. 6. The internal lumen support of claim 1 wherein said first and second projections take the form of tissue anchoring elements.

1. 7. The internal lumen support of claim 1 wherein said first and second projections take the form of spikes.

- 1 8. The internal lumen support of claim 7 wherein said first projection extends generally
2 perpendicular from an end surface of said first end and said second projection extends
3 generally perpendicular from an end surface of said second end.

- 1 9. The internal lumen support of claim 7 wherein said spikes are curved.

- 1 10. The internal lumen support of claim 7 wherein said spike extends at an angle from a
2 longitudinal axis of said body.

- 1 11. The internal lumen support of claim 10 wherein said angle is between 0 and 90
2 degrees.

- 1 12. The internal lumen support of claim 10 wherein said angle is between 0 and 75
2 degrees.

- 1 13. The internal lumen support of claim 10 wherein said angle is between 0 and 45
2 degrees.

- 1 14. The internal lumen support of claim 10 wherein said angle is between 0 and 30
2 degrees.

- 1 15. The internal lumen support of claim 1 wherein said first projection is one of a plurality
2 of projections extending from said first end of said body and said second projection is one
3 of a plurality of projections extending from said second end of said body.

- 1 16. The internal lumen support of claim 1 wherein said first projection extends from a first
2 non-penetrating distal surface sized and configured to inhibit penetration of said first end
3 into the wall of the lumen and wherein said second projection extends from a second non-

- 4 penetrating distal surface sized and configured to inhibit penetration of said second end
5 into the wall of the lumen.

- 1 17. The internal lumen support of claim 1 wherein said first end has a first shoulder
2 extending around a periphery thereof, said first shoulder sized and configured to inhibit
3 penetration of said first end into the wall of the lumen and wherein said second end has a
4 second shoulder extending around a periphery thereof, said second shoulder sized and
5 configured to inhibit penetration of said second end into the wall of the lumen.

- 1 18. The internal lumen support of claim 1 wherein the wall of the lumen has an interior
2 layer and an exterior layer, wherein said first and second projections are sized and
3 configured to extend through the interior layer and lodge within the exterior layer, and
4 wherein said first end has a blunt end surface sized and configured to inhibit penetration of
5 said first end into the exterior layer of the lumen and wherein said second end has a blunt
6 end surface sized and configured to inhibit penetration of said second end into the exterior
7 layer of the lumen.

- 1 19. The internal lumen support of claim 1 further comprising a hinge between said first
2 end and said second end, thereby allowing said body to fold at said hinge.

- 1 20. The internal lumen support of claim 19 wherein said hinge has a lock configured to
2 hold said internal lumen support in said open position.

- 1 21. The internal lumen support of claim 1 further comprising a spring between said first
2 end and said second end, thereby allowing said body to compress by compressing said
3 spring.

- 1 22. The internal lumen support of claim 1 wherein said internal lumen support is formed
2 from a biodegradable material.

- 1 23. The internal lumen support of claim 1 wherein said internal lumen support is formed
2 of a biodegradable material selected from the group of biodegradable materials consisting
3 of poly-lactate, poly-glycolate, collagen, elastin and gelatin.

- 1 24. The internal lumen support of claim 1 wherein said support is formed of stainless
2 steel.

- 1 25. The internal lumen support of claim 1 wherein said internal lumen support is formed
2 of a nickel-titanium alloy.

- 1 26. The internal lumen support of claim 25 wherein said nickel-titanium alloy is chosen
2 for super-elastic properties.

- 1 27. The internal lumen support of claim 25 wherein said nickel-titanium alloy is chosen
2 for shape memory properties.

- 1 28. The internal lumen support of claim 1 wherein said internal lumen support is formed
2 of a durable polymer.

- 1 29. The internal lumen support of claim 1 wherein said internal lumen support is formed
2 of a durable polymer chosen from the group of durable polymers consisting of
3 polyetheretherketone, polysulfone, polyethylene, polypropylene, polycarbonate,
4 polyurethane, polyvinyl chloride, polyimide, delrin and polytetrafluoroethylene.

- 1 30. The internal lumen support of claim 1 wherein said body is formed from a plurality of
2 parts.

- 1 31. The internal lumen support of claim 30 wherein one of said plurality of parts is formed
2 of a biodegradable material and a second of said plurality of parts is formed of a non-
3 biodegradable material.

- 1 32. The internal lumen support of claim 1 wherein said internal lumen support has a
2 coating.

- 1 33. The internal lumen support of claim 1 wherein said internal lumen support has a
2 coating chosen from the group of coatings consisting of a lubricious coating, a
3 biocompatible coating, an anticorrosive coating, an antibiotic coating, a coating containing
4 a growth factor, a coating containing a hormone, a time-release coating, a radiopaque
5 coating, an echogenic coating, a radioactive coating and a plasma coating.

- 1 34. The internal lumen support of claim 1 wherein said internal lumen support has a
2 coating chosen from the group of coatings consisting of a tissue sealing coating, a
3 hydrophilic coating, a hydrophobic coating and a coating containing a drug.

- 1 35. The internal lumen support of claim 1 wherein said first and second ends are
2 configured to promote the ingrowth of tissue.

- 1 36. The internal lumen support of claim 1 wherein said internal lumen support is a first
2 internal lumen support and further comprising a second internal lumen support positioned
3 in a spaced-apart relationship with respect to said first internal lumen support.

- 1 37. The internal lumen support of claim 36 further comprising a third internal lumen
2 support positioned in a spaced-apart relationship with respect to said first and second
3 internal lumen supports.

- 1 38. The internal lumen support of claim 37 further comprising a rod connecting said first,
2 second and third internal lumen support, thereby creating a sphincteric shaper.

- 1 39. The internal lumen support of claim 38 wherein said rod has a curvature.

- 1 40. The internal lumen support of claim 38 wherein said rod is formed of a shape memory
- 2 material.

- 1 41. The internal lumen support of claim 38 wherein said rod has elastic properties.

- 1 42. The internal lumen support of claim 37 further comprising a rod and wherein said
- 2 first, second and third internal lumen support each have an opening extending
- 3 therethrough, said rod being sized and configured to pass through said openings.

- 1 43. The internal lumen support of claim 37 further comprising a separator sized and
- 2 configured to hold said first and second internal lumen support at least a first pre-selected
- 3 distance apart and a second separator sized and configured to hold said second and third
- 4 internal lumen support at least a second pre-selected distance apart.

- 1 44. The internal lumen support of claim 36 further comprising a connector connecting
- 2 said first and second internal lumen support.

- 1 45. The internal lumen support of claim 36 further comprising a rod and wherein said first
- 2 and second support devices each have an opening extending therethrough, said rod being
- 3 sized and configured to pass through said openings.

- 1 46. The internal lumen support of claim 45 wherein said rod has an end cap, said end cap
- 2 being sized and configured to prevent said end cap from passing through one of said
- 3 openings.

- 1 47. The internal lumen support of claim 46 wherein said end cap is detachably attached to
- 2 said rod.

- 1 48. The internal lumen support of claim 45 further comprising at least one separator sized
- 2 and configured to hold said first and second support devices at least a pre-selected
- 3 distance apart.

- 1 49. The internal lumen support of claim 45 further comprising at least one separator
- 2 located around said rod.

- 1 50. The internal lumen support of claim 49 wherein said separator is a spring.

- 1 51. The internal lumen support of claim 50 wherein said spring is located between one of
- 2 said support devices and an end of said rod.

- 1 52. The internal lumen support of claim 50 wherein said first internal lumen support is
- 2 movable between a first position and a second position and wherein in said first position
- 3 said spring is loaded and wherein in said second position said spring is relaxed.

- 1 53. The internal lumen support of claim 49 wherein said separator is a tubular member.

- 1 54. The internal lumen support of claim 49 wherein said separator is formed of a
- 2 biodegradable material.

- 1 55. The internal lumen support of claim 49 wherein said separator is flexible.

- 1 56. The internal lumen support of claim 45 wherein said rod has a generally square cross-
2 section.

- 1 57. The internal lumen support of claim 1 further comprising a second internal lumen
- 2 support, a tubular member extending from said first internal lumen support and a post
- 3 extending from said second internal lumen support, said post being sized and configured
- 4 to fit at least partially within said tubular member.

1 58. The internal lumen support of claim 1 wherein at least a portion of said internal lumen
2 support is formed of a magnetic material.

1 59. A delivery device for delivering the internal lumen support of claim 1, the delivery
2 device comprising:

3 a generally tubular member having a chamber therein, said chamber sized and
4 configured to hold at least one of said internal lumen support,
5 a plunger at least partially located within said chamber and movable along a
6 longitudinal axis of said tubular member,
7 and an opening into said tubular member in a distal portion thereof, said opening
8 being sized and configured to allow said internal lumen support to pass
9 therethrough when said internal lumen support is in said closed position.

1 60. The delivery device of claim 59 wherein said opening within said tubular member is
2 rectangular.

1 61. The delivery device of claim 59 wherein said opening is centered within a distal end of
2 said distal portion of said tubular member.

1 62. The delivery device of claim 59 wherein said opening is off-center within a distal end
2 of said distal portion of said tubular member.

1 63. The delivery device of claim 59 wherein said chamber is at a non-zero angle to a
2 longitudinal axis of said tubular member.

1 64. The delivery device of claim 59 wherein said tubular member is sized and configured
2 to fit within a urethra.

- 1 65. The delivery device of claim 59 further comprising an orientation line located on an
2 exterior surface of said tubular member and extending along a longitudinal axis of said
3 tubular member.
- 1 66. The delivery device of claim 59 further comprising a plurality of insertion markers,
2 said insertion markers located on an exterior surface of said tubular member.
- 1 67. The delivery device of claim 59 wherein said chamber is sized and configured to hold
2 a plurality of said internal lumen supports.
- 1 68. The delivery device of claim 59 wherein said tubular member and said plunger are
2 formed of a flexible material.
- 1 69. The delivery device of claim 59 wherein said internal lumen support is in said closed
2 position within said chamber.
- 1 70. An internal lumen support for altering the configuration of a soft hollow, tubular body
2 having a lumen and a wall with a resilient interior surface, the internal lumen support
3 comprising:
 - 4 a generally rigid body having a first end, a second end and a middle portion,
 - 5 a first projection extending from said first end,
 - 6 and a second projection extending from said second end,

7 wherein said internal lumen support has a delivery position and a deployed position,
8 and wherein said deployed position of said internal lumen support is approximately
9 perpendicular to said delivery position of said internal lumen support.
- 1 71. The internal lumen support of claim 70 wherein said first and second projections take
2 the form of tissue anchoring elements.

- 1 72. The internal lumen support of claim 70 wherein said first and second projections take
2 the form of spikes.
- 1 73. The internal lumen support of claim 72 wherein said first projection extends generally
2 perpendicular from an end surface of said first end and said second projection extends
3 generally perpendicular from an end surface of said second end.
- 1 74. The internal lumen support of claim 72 wherein said spikes are curved.
- 1 75. The internal lumen support of claim 70 wherein said first projection extends from a
2 first non-penetrating distal surface sized and configured to inhibit penetration of said first
3 end into the wall of the lumen and wherein said second projection extends from a second
4 non-penetrating distal surface sized and configured to inhibit penetration of said second
5 end into the wall of the lumen.
- 1 76. The internal lumen support of claim 70 wherein said first end has a first shoulder
2 extending around a periphery thereof, said first shoulder sized and configured to inhibit
3 penetration of said first end into the wall of the lumen and wherein said second end has a
4 second shoulder extending around a periphery thereof, said second shoulder sized and
5 configured to inhibit penetration of said second end into the wall of the lumen.
- 1 77. The internal lumen support of claim 70 wherein the wall of the lumen has an interior
2 layer and an exterior layer, wherein said first and second projections are sized and
3 configured to extend through the interior layer and lodge within the exterior layer, and
4 wherein said first end has a blunt end surface sized and configured to inhibit penetration of
5 said first end into the exterior layer of the lumen and wherein said second end has a blunt
6 end surface sized and configured to inhibit penetration of said second end into the exterior
7 layer of the lumen.

- 1 78. The internal lumen support of claim 70 wherein said first and second ends are
- 2 configured to promote the ingrowth of tissue.

- 1 79. A spacer for placement within the bladder neck of a patient during a partial ligation
- 2 procedure, the spacer comprising:
 - 3 an elongated flexible spacer member having a proximal portion and a distal portion,
 - 4 said proximal portion being generally D-shaped and said distal portion being
 - 5 generally round, said spacer member being pinch-resistant, said spacer being
 - 6 sized and configured to reach the bladder neck through the patient's urethra.

- 1 80. The spacer member of claim 79 wherein said spacer member has a lumen passing
- 2 therethrough.

- 1 81. The spacer member of claim 79 wherein said generally round member has an exterior
- 2 diameter of between 1 and 10 millimeters.

- 1 82. The spacer member of claim 79 wherein said spacer member has a plurality of
- 2 insertion markers.

- 1 83. The spacer member of claim 79 wherein said spacer member has an orientation line
- 2 extending along a longitudinal axis of said spacer member.

- 1 84. The spacer member of claim 79 in combination with bladder filling equipment.

- 1 85. The internal lumen support of claim 1 wherein said lumen is a urethra, and wherein
- 2 said internal lumen support is an internal urethral support.

- 1 86. A method of treating a dysfunction of the urinary tract, the method comprising the
- 2 steps of:
 - 3 (a) inserting a delivery device into a urethra;

- 4 (b) deploying an internal urethral support within the urethra in a transverse
5 orientation with respect to the urethra;
- 6 (c) and withdrawing said delivery device from the urethra.

1 87. The method of claim 86 wherein said internal urethral support is deployed within the
2 urethra at the urethral sphincter.

1 88. The method of claim 86 wherein said internal urethral support is deployed to reshape
2 the urethra when the urethra is in a rest position.

1 89. The method of claim 86 wherein said internal urethral support is deployed to treat
2 urinary incontinence.

1 90. The method of claim 89 wherein said internal urethral support is deployed in a central
2 portion of a cross section of the urethra.

1 91. The method of claim 89 wherein said internal urethral support is deployed proximate
2 a posterior wall of the urethra.

1 92. The method of claim 89 wherein multiple internal urethral supports are deployed
2 within the urethra.

1 93. The method of claim 89 further comprising the step of:
2 (d) manipulating said internal urethral support to move from a delivery position
3 within said delivery device to a deployed position within the urethra.

1 94. The method of claim 93 wherein said delivery position is a closed position and said
2 deployed position is an opened position.

- 1 95. The method of claim 93 wherein said delivery position is a closed position and said
2 deployed position is an opened position and wherein, when said internal urethral support is
3 in said open position said internal urethral support is relaxed.

- 1 96. The method of claim 93 wherein, when said internal urethral support is in said
2 deployed position within the urethra, said internal urethral support is stretching a lateral
3 wall of the urethra.

- 1 97. The method of claim 93 wherein, when said internal urethral support is in said
2 deployed position within the urethra, said internal urethral support is stretching a posterior
3 wall of the urethra.

- 1 98. The method of claim 93 wherein, when said internal urethral support is in said
2 deployed position within the urethra, said internal urethral support is stretching and
3 supporting a posterior wall of the urethra.

- 1 99. The method of claim 93 wherein, when said internal urethral support is in said
2 deployed position within the urethra, said internal urethral support is stiffening a posterior
3 wall of the urethra.

- 1 100. The method of claim 93 wherein, when said internal urethral support is in said
2 deployed position within the urethra, said internal urethral support is strengthening a
3 posterior wall of the urethra.

- 1 101. The method of claim 93 wherein, when said internal urethral support is in said
2 deployed position within the urethra, said internal urethral support is reshaping a rest
3 position of a posterior wall of the urethra.

- 1 102. The method of claim 93 further comprising the steps of:

2 (e) holding said internal urethral support in place by at least one projection
3 extending into a wall of the urethra.

1 103. The method of claim 93 further comprising the steps of:
2 (e) holding said internal urethral support in place by at least one projection
3 extending through a layer of mucosa and into muscle, the layer of mucosa and
4 the muscle forming a wall of the urethra.

1 104. The method of claim 89 wherein said internal urethral support is deployed within the
2 sphincter urethrae and further comprising the steps of:
3 (d) deploying a second and third internal urethral support within the urethra;
4 (e) and deploying a rod within the urethra;
5 wherein said internal urethral supports and said rod form a sphincteric shaper and said
6 sphincteric shaper changes a rest position of the sphincter urethrae.

1 105. The method of claim 104 wherein said internal urethral supports and said rod are
2 deployed as a single unit.

1 106. The method of claim 89 wherein said internal urethral support is a first magnetic
2 internal urethral support and further comprising the step of:
3 (d) positioning and deploying a second magnetic internal urethral support in a
4 position within the urethra and opposite from said first magnetic internal urethral
5 support.

1 107. The method of claim 106 wherein said first magnetic internal urethral support is
2 deployed proximate a posterior wall of the urethra and second magnetic internal urethral
3 support is deployed proximate an anterior wall of the urethra.

1 108. The method of claim 107 further comprising the step of:

2 (e) stretching the posterior and anterior wall of the urethra with said magnetic
3 internal urethral supports, thereby placing the posterior and anterior walls closer
4 together.

1 109. The method of claim 89 further comprising the steps of:

2 (d) deploying a second internal urethral support within the urethra;
3 (e) and deploying a spring within the urethra;

4 and wherein said internal urethral supports and said spring form a urethra extensor.

1 110. The method of claim 109 wherein said internal urethral supports and said spring are
2 deployed as a single unit.

1 111. The method of claim 109 wherein said urethral extensor stretches a longitudinal axis
2 of the urethra, thereby extending a length of the urethra.

1 112. The method of claim 109 wherein said urethral extensor reshapes the urethra such
2 that a posterior wall and an anterior wall of the urethra are closer together.

1 113. The method of claim 86 wherein said internal urethral support is deployed to treat a
2 urinary obstruction.

1 114. The method of claim 113 further comprising the step of:

2 (d) allowing said internal urethral support to press against an obstructive tissue
3 within the urethra.

1 115. The method of claim 114 wherein, when said internal urethral support is in a
2 deployed position within the urethra, said internal urethral support is stretching a lateral
3 wall of the urethra.

- 1 116. The method of claim 114 wherein, when said internal urethral support is in a
2 deployed position within the urethra, said internal urethral support is stretching a posterior
3 wall of the urethra.

- 1 117. The method of claim 114 wherein, when said internal urethral support is in a
2 deployed position within the urethra, said internal urethral support is stretching and
3 supporting a lateral wall of the urethra.

- 1 118. The method of claim 114 wherein, when said internal urethral support is in a
2 deployed position within the urethra, said internal urethral support is stiffening a posterior
3 wall of the urethra.

- 1 119. The method of claim 114 wherein, when said internal urethral support is in a
2 deployed position within the urethra, said internal urethral support is stretching an anterior
3 wall of the urethra.

- 1 120. The method of claim 114 wherein, when said internal urethral support is in a
2 deployed position within the urethra, said internal urethral support is reshaping a position
3 of a posterior wall of the urethra.

- 1 121. The method of claim 114 further comprising the step of:
2 (e) holding said internal urethral support in place by at least one projection
3 extending into a wall of the urethra.

- 1 122. The method of claim 114 further comprising the step of deploying a second internal
2 urethral support within said urethra.

- 1 123. The method of claim 113 wherein said internal urethral support is deployed within
2 the urethra at the urethral sphincter.

- 1 124. The method of claim 113 further comprising the step of:
 - 2 (d) opening the urinary obstruction with the assistance of a spring located around a
 - 3 rod extending between said internal urethral support and a second internal
 - 4 urethral support.
- 1 125. The method of claim 89 wherein said internal urethral support is formed of a
2 generally rigid material and is deployed by the step of:
 - 3 (d) rotating the internal urethral support from a delivery position to a deployed
 - 4 position.
- 1 126. A method of promoting bladder neck closure with partial ligation to treat urinary
2 incontinence, the method comprising the steps of:
 - 3 (a) inserting a spacer through a urethra into a bladder;
 - 4 (b) threading a suture behind and around the bladder neck;
 - 5 (c) tying said suture around the bladder neck;
 - 6 (d) withdrawing said spacer.
- 1 127. The method of claim 126 wherein said suture is threaded behind the bladder neck
2 using an endoscopic suture device.
- 1 128. The method of claim 126 wherein said suture has an external urethral support
2 attached thereto, said external urethral support being placed against an exterior surface of
3 the bladder neck.
- 1 129. The method of claim 126 wherein said suture is secured with a locking device.
- 1 130. The method of claim 126 wherein said suture is cut after securing.
- 1 131. The method of claim 126 further comprising the step of repeating steps (a) through
2 (d) to place a second suture around the bladder neck.

- 1 132. The method of claim 126 wherein said suture is a band-like material.
- 1 133. The method of claim 126 further comprising the steps of:
 - 2 (e) filling the bladder with medium through said spacer;
 - 3 (f) and checking for medium leakage.
- 1 134. The method of claim 133 further comprising the steps of filling the bladder of the patient to more than 10 cm of water pressure.
- 1 135. The method of claim 133 further comprising the steps of filling the bladder of the patient to less than 86 cm water pressure.
- 1 136. The method of claim 133 wherein the bladder of the patient is filled with less than 2 1000 cc of medium.
- 1 137. The method of claim 133 wherein step (e) is performed by filling the bladder with a 2 liquid medium.
- 1 138. The method of claim 133 wherein step (e) is performed by filling the bladder with a 2 colored liquid medium.
- 1 139. A method of promoting closing of a urethra with partial ligation to treat urinary 2 incontinence, the method comprising the steps of:
 - 3 (a) inserting a spacer into the urethra;
 - 4 (b) threading a suture behind and around the urethra;
 - 5 (c) tying the suture around the urethra;
 - 6 (d) withdrawing said spacer.

- 1 140. The method of claim 139 wherein said suture is threaded behind the urethra using an
2 endoscopic suture device.
- 1 141. The method of claim 139 wherein said suture has an external urethral support
2 attached thereto, said external urethral support being placed against an exterior surface of
3 the urethra.
- 1 142. The method of claim 139 wherein said suture is secured with a locking device.
- 1 143. The method of claim 139 wherein said suture is cut after securing.
- 1 144. The method of claim 139 further comprising the step of repeating steps (a) through
2 (d) to place a second suture around the urethra.
- 1 145. The method of claim 139 wherein said suture is a band-like material
- 1 146. The method of claim 139 further comprising the steps of:
2 (e) filling the bladder with medium through said spacer;
3 (f) and checking for medium leakage.
- 1 147. The method of claim 146 further comprising the steps of filling the bladder of the
2 patient to more than 10 cm of water pressure.
- 1 148. The method of claim 146 further comprising the steps of filling the bladder of the
2 patient to less than 100 cm water pressure.
- 1 149. The method of claim 146 wherein the bladder of the patient is filled with less than
2 1000 cc of medium.

1 150. The method of claim 146 wherein step (e) is performed by filling the bladder with a
2 liquid medium.

1 151. The method of claim 146 wherein step (e) is performed by filling the bladder with a
2 colored liquid medium.

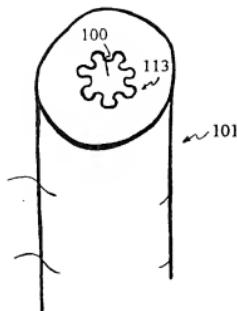


Figure 1

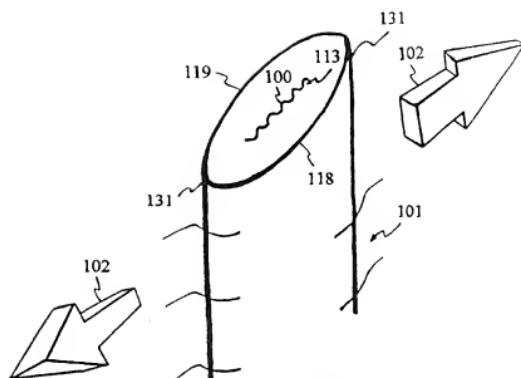


Figure 2

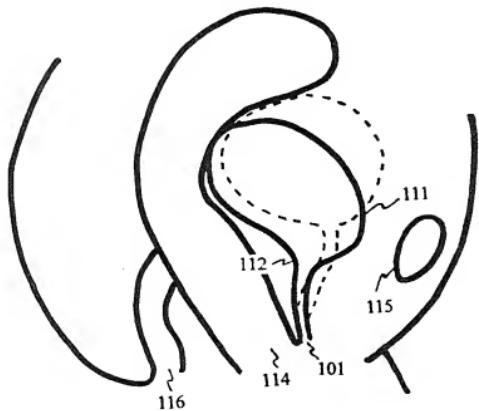


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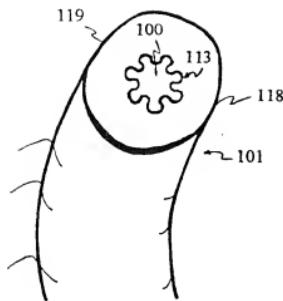


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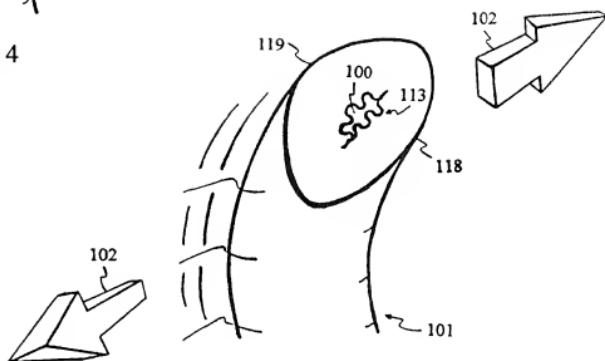


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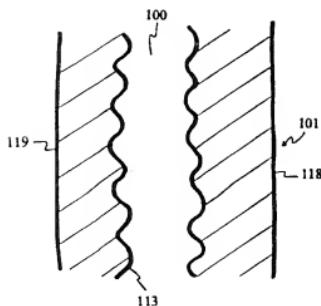


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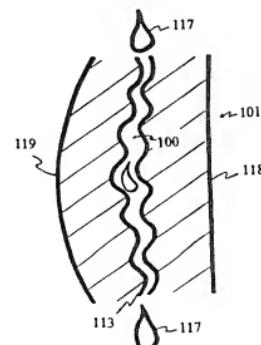


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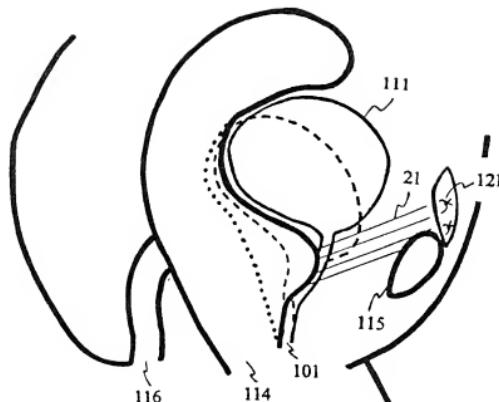


Figure 8
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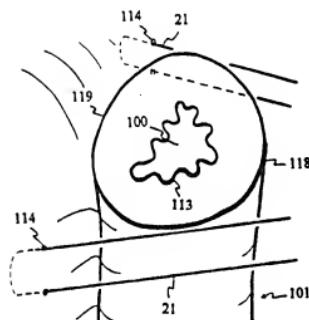


Figure 9
Prior Art

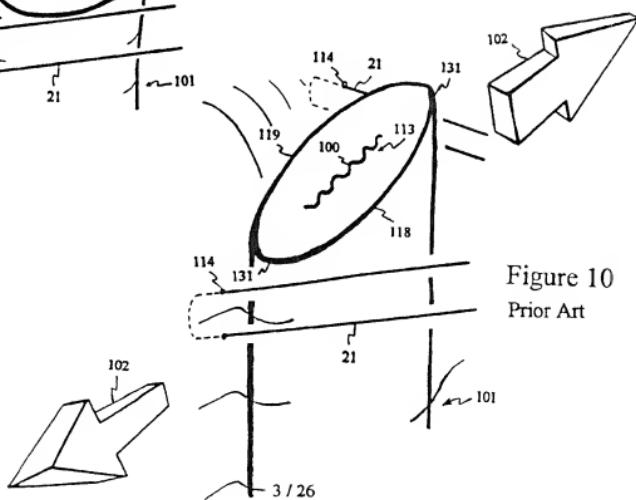


Figure 10
Prior Art

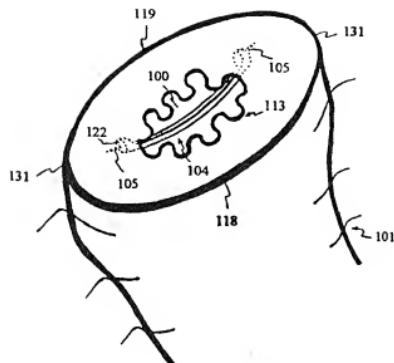


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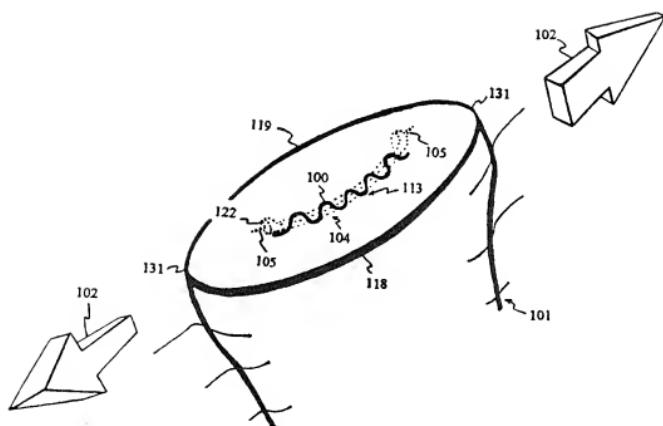


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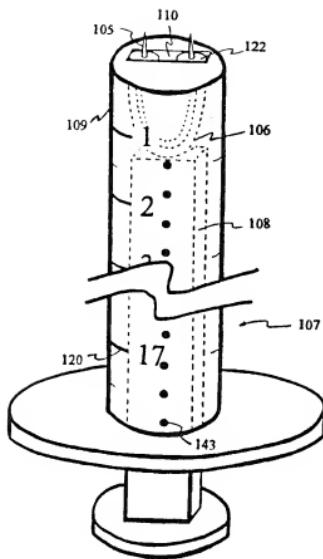


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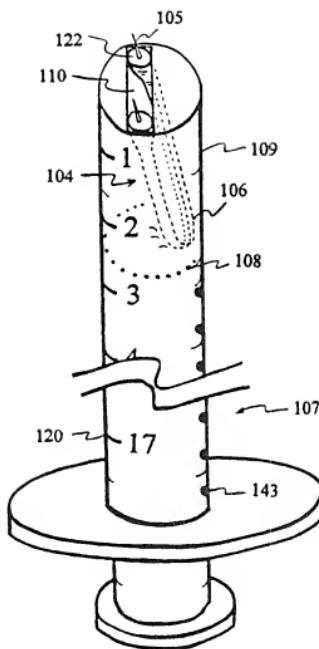


Figure 19

Figure 20

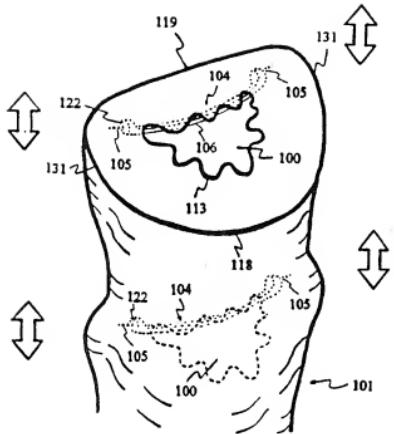
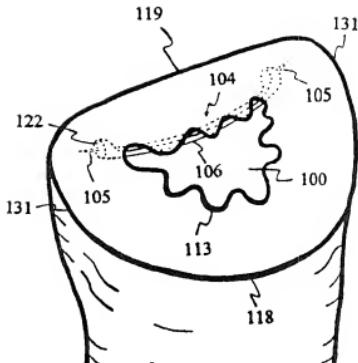


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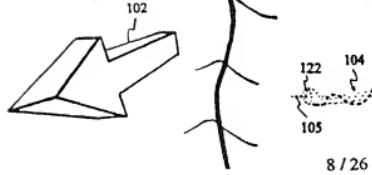
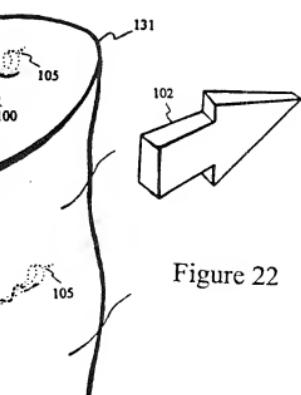


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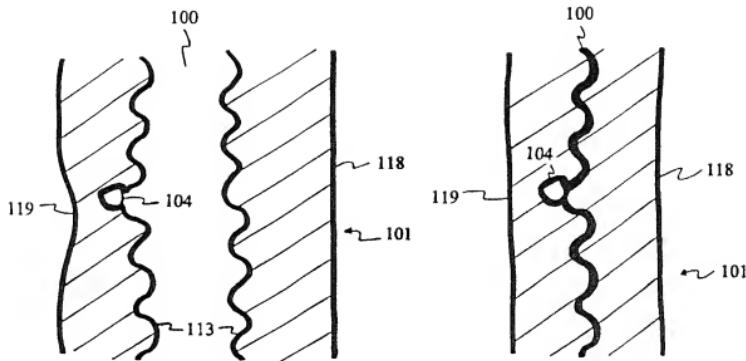


Figure 23

Figure 24

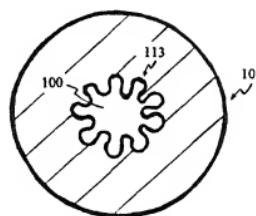


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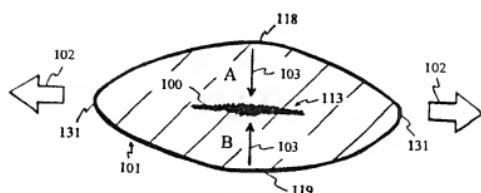


Figure 26

Figure 27

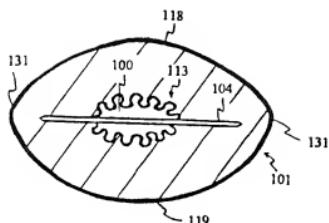
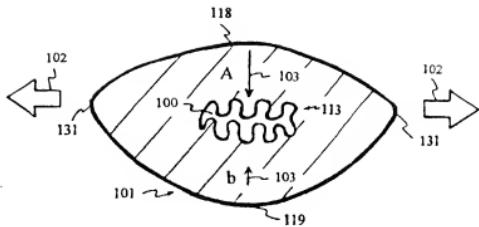


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Figure 29

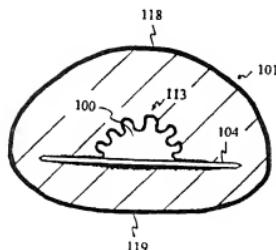
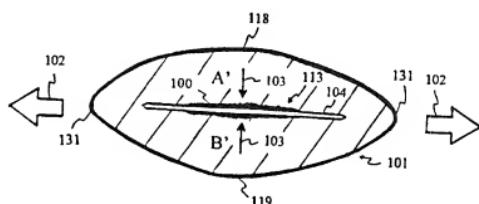
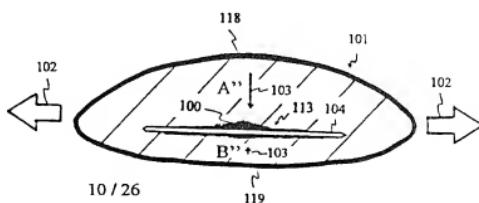


Figure 30

Figure 31



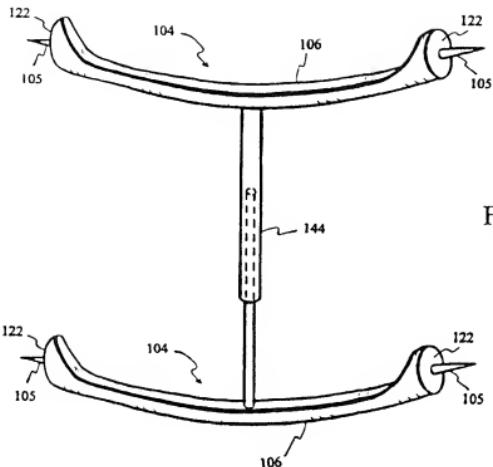


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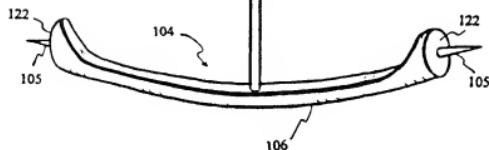


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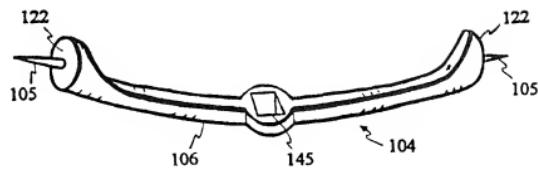
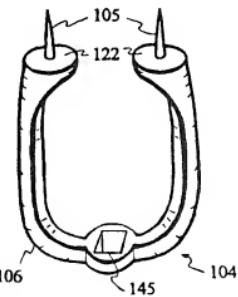


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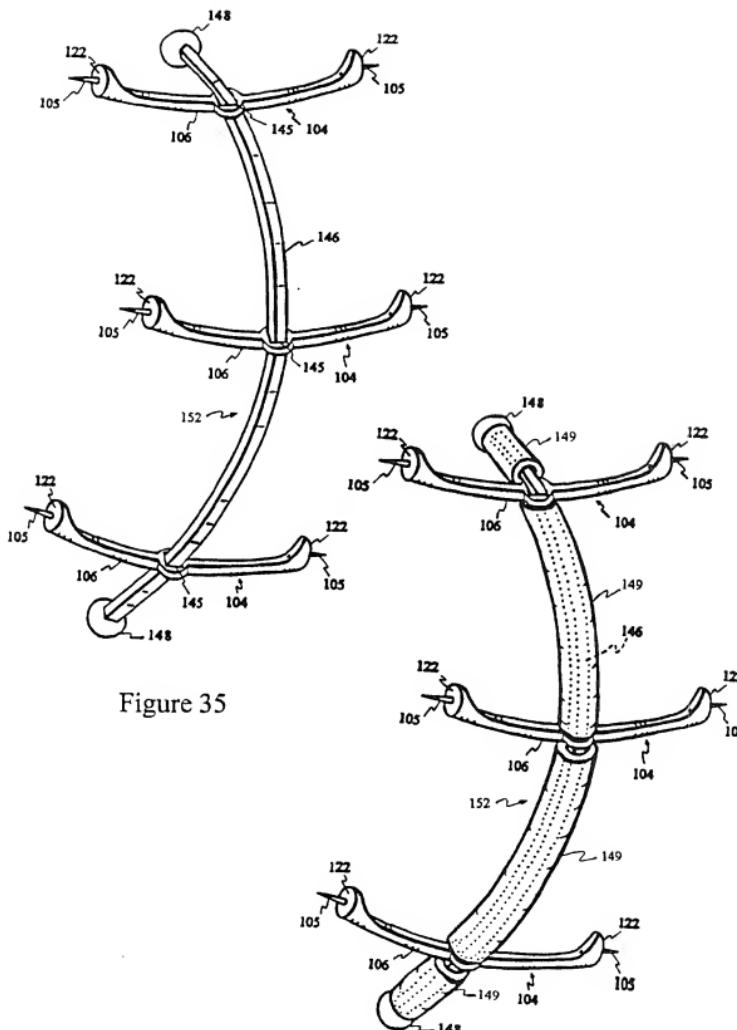


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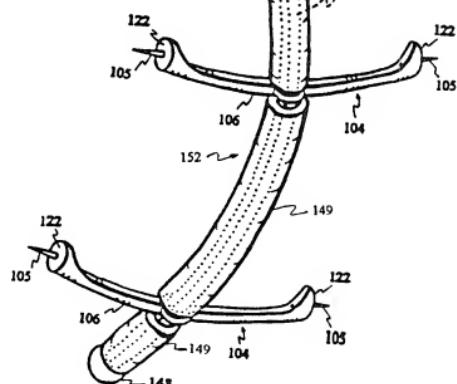


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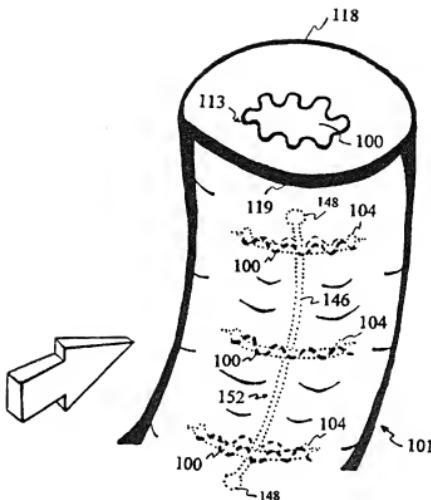


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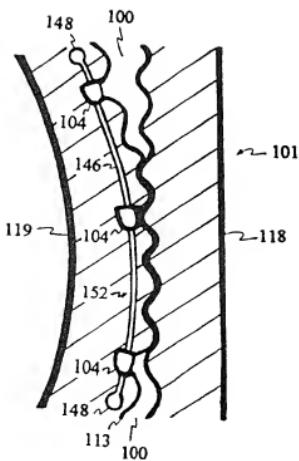


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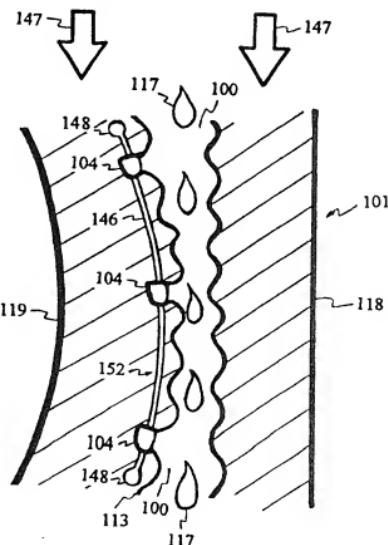


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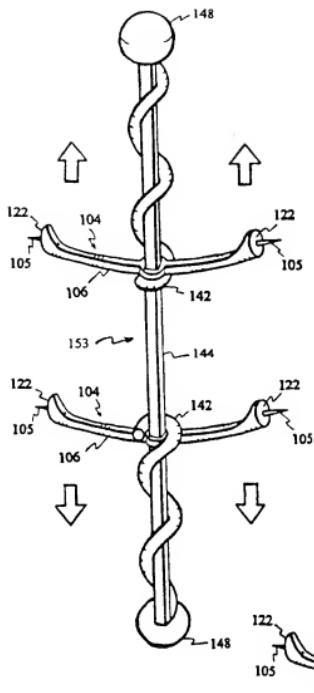


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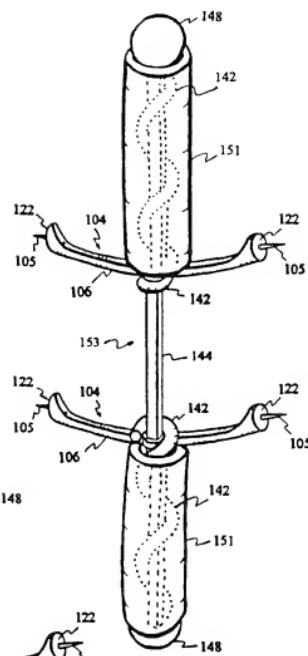


Figure 41



Figure 42

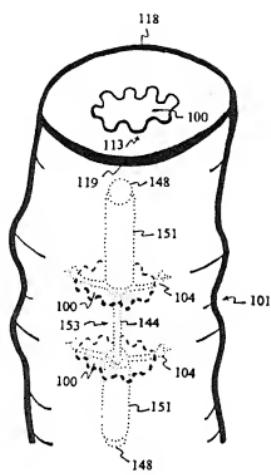


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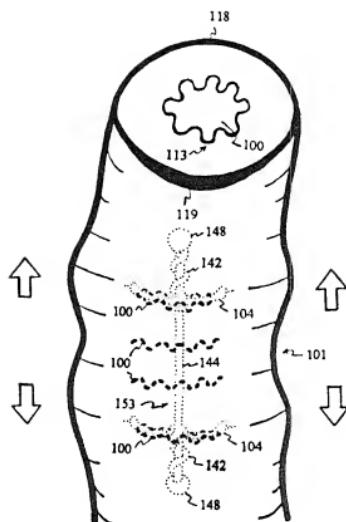


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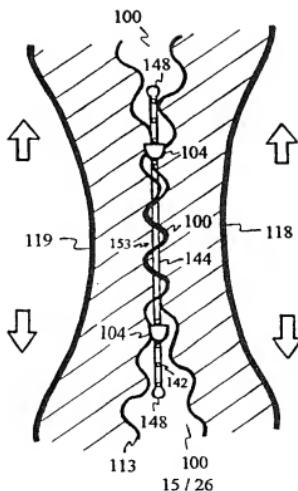


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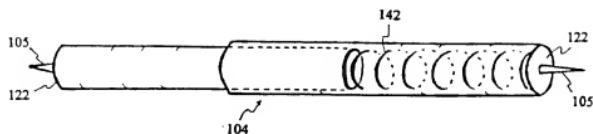


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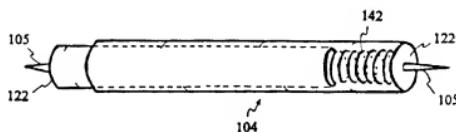


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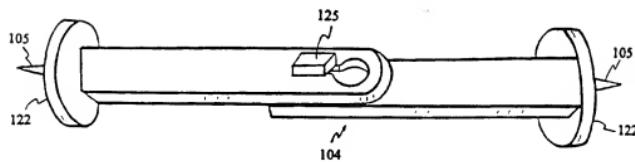


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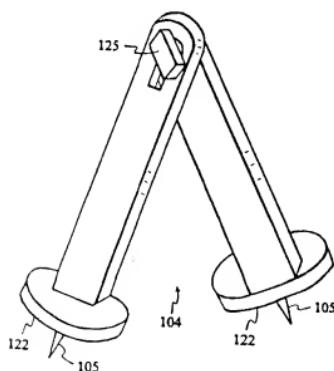


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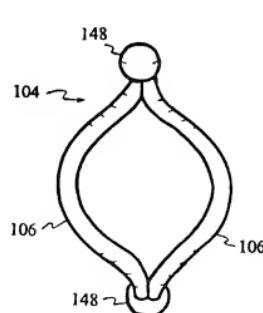


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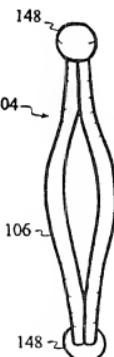


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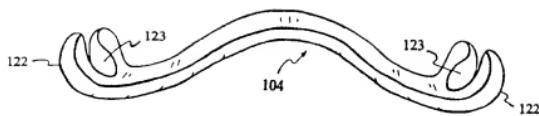


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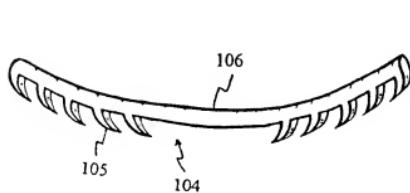


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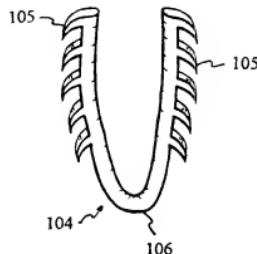


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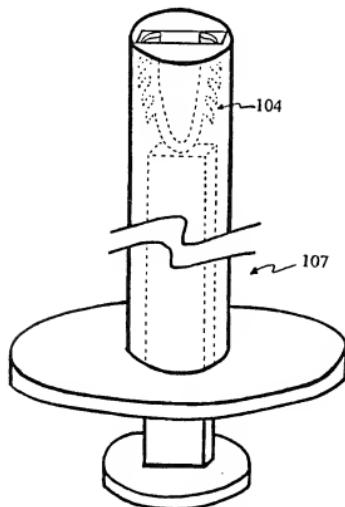


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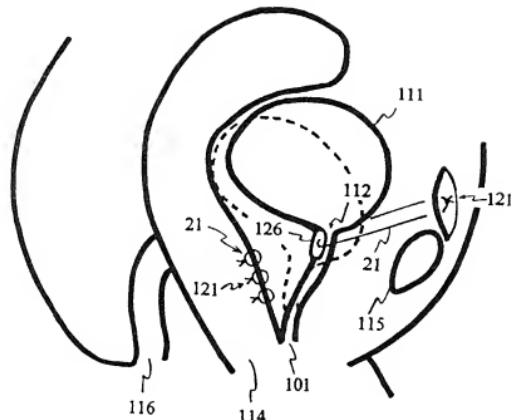


Figure 56
Prior Art

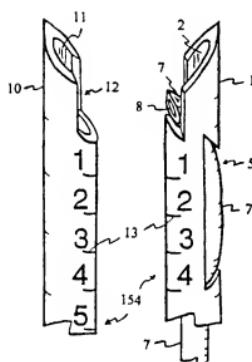


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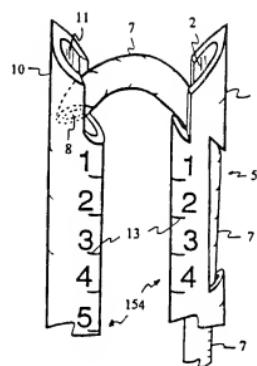


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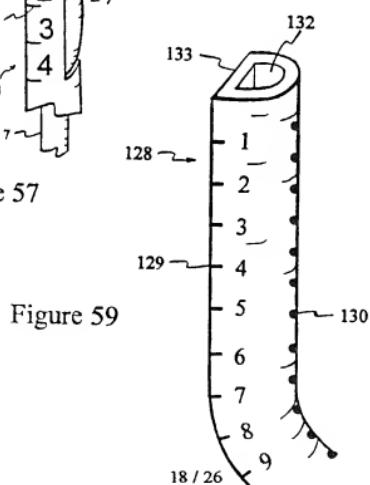


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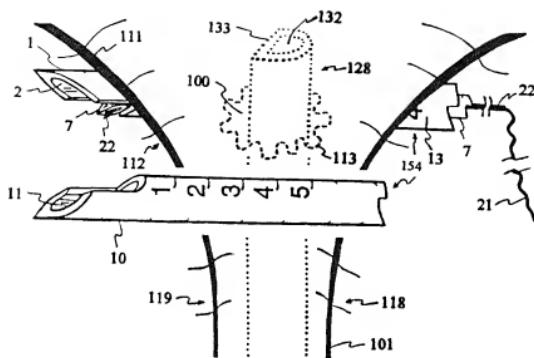


Figure 60

Figure 61

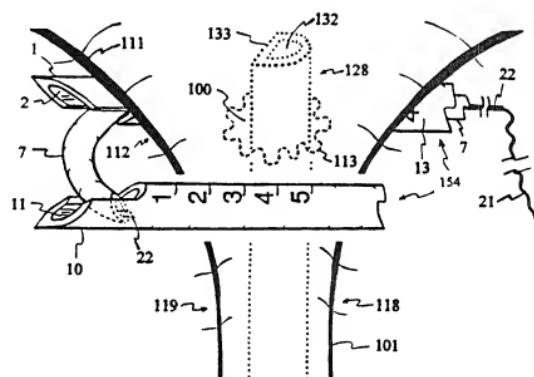
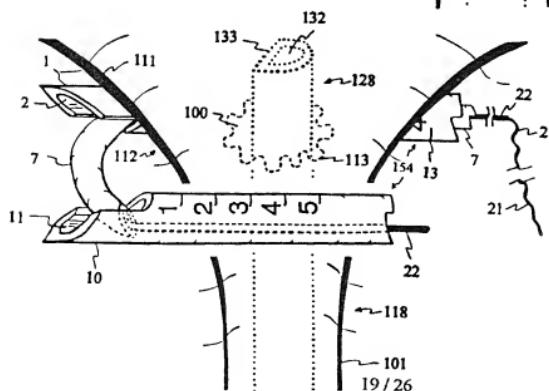


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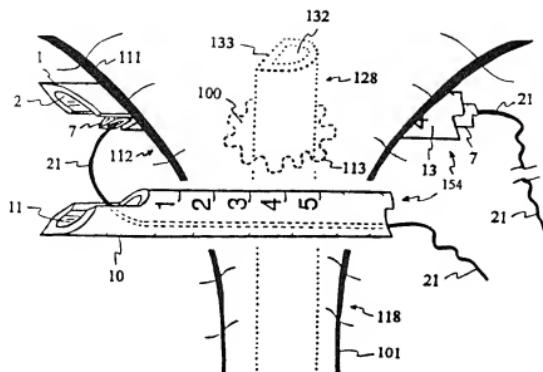


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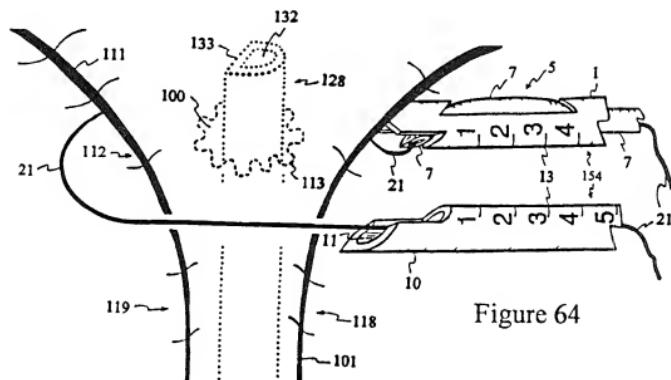


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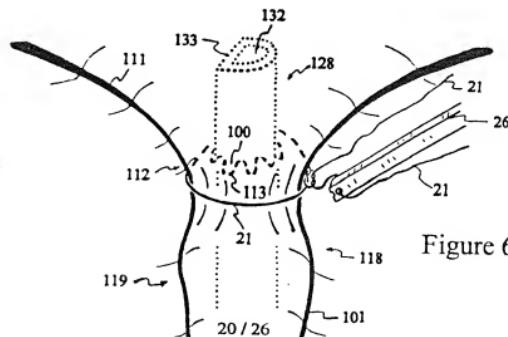


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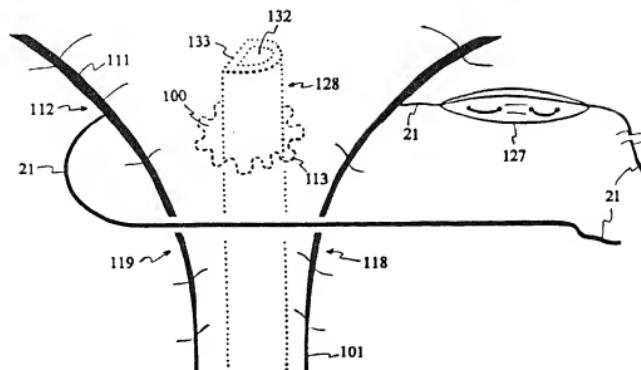


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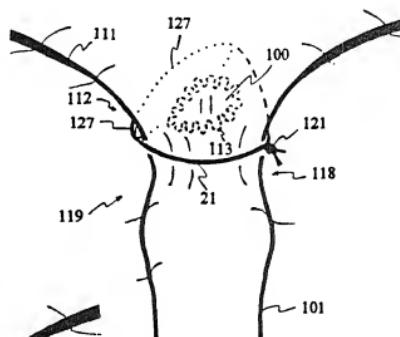


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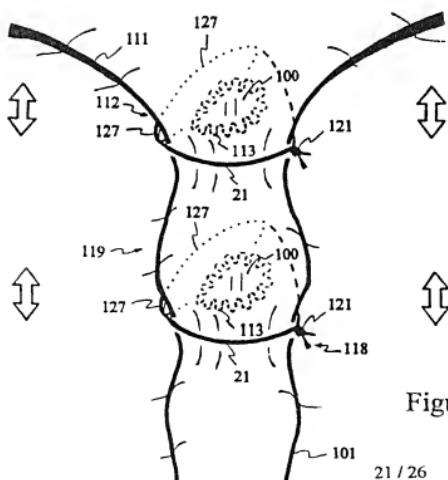


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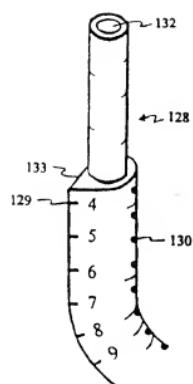


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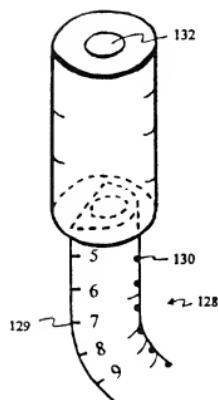


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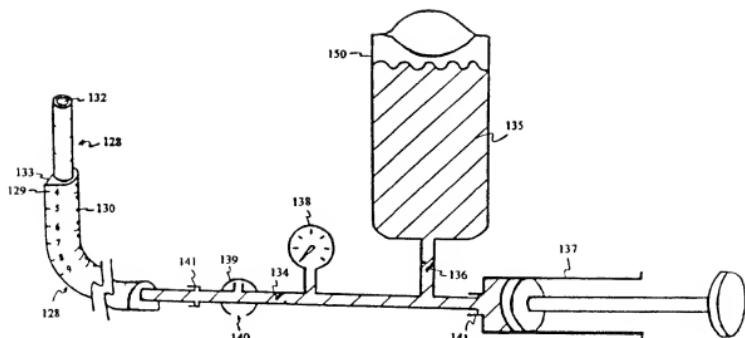


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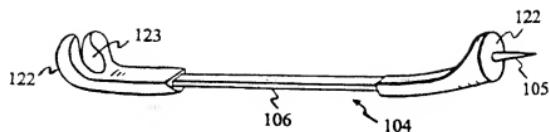


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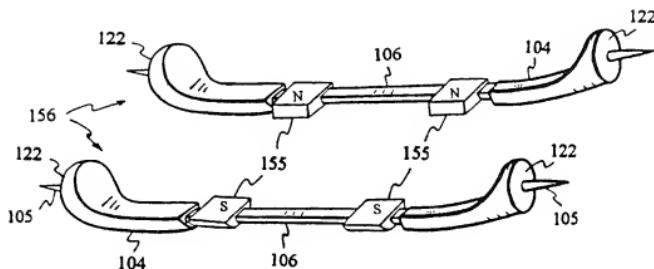


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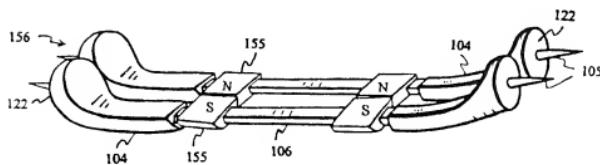


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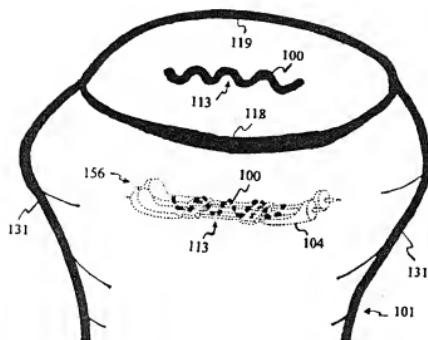


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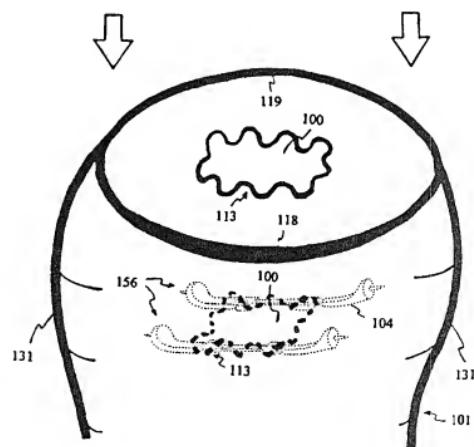


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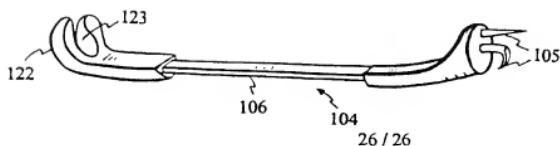


Figure 80